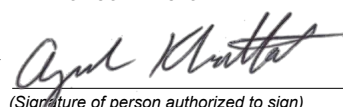



<b>AWARD/CONTRACT</b>		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING		PAGE OF PAGES 1   81	
2. CONTRACT (Proc. Inst. Ident.) NO. HHSO100201800016C				3. EFFECTIVE DATE See Block 20C		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. OS221221	
5. ISSUED BY CODE		ASPR-BARDA		6. ADMINISTERED BY (If other than Item 5) CODE		ASPR-BARDA02	
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201				US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515			
7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code)  Cue Health Inc. 11100 Roselle St STE A San Diego, CA 92121-1210				8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT			
				10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN			
CODE		FACILITY CODE					
11. SHIP TO/MARK FOR CODE		HHS/OS/ASPR		12. PAYMENT WILL BE MADE BY CODE		ASPR/BARDA01	
HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201				ASPR/BARDA01 200 C St SW Washington DC 20201			
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304 (c) ( ) <input type="checkbox"/> 41 U.S.C. 253 (c) ( )				14. ACCOUNTING AND APPROPRIATION DATA 2018.199TWNQ.25106			
15A. ITEM NO	15B. SUPPLIES/SERVICES			15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued						
15G. TOTAL AMOUNT OF CONTRACT						\$14,000,000.00	
<b>16. TABLE OF CONTENTS</b>							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	48
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	10	X	J	LIST OF ATTACHMENTS	53
X	D	PACKAGING AND MARKING	18	PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	19		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	20		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	G	CONTRACT ADMINISTRATION DATA	33		M	EVALUATION FACTORS FOR AWARD	
X	H	SPECIAL CONTRACT REQUIREMENTS	39				
<b>CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE</b>							
17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return <u>1</u> copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. <input type="checkbox"/> SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)			
19A. NAME AND TITLE OF SIGNER (Type or print)				20A. NAME OF CONTRACTING OFFICER SALIM K. ROBERTS			
19B. NAME OF CONTRACTOR		19C. DATE SIGNED		20B. UNITED STATES OF AMERICA		20C. DATE SIGNED	
BY  (Signature of person authorized to sign)		06/04/2018		BY  (Signature of the Contracting Officer)		4JUN2018	

**CONTINUATION SHEET**

 REFERENCE NO. OF DOCUMENT BEING CONTINUED  
 HHSO100201800016C

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NAME OF OFFEROR OR CONTRACTOR

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: DUNS Number: 016813796 Cue Health Inc: for the development of a first-in-class reusable platform-based influenza in vitro diagnostic (IVD) test for in-home use Appr. Yr.: 2018 CAN: 199TWNQ Object Class: 25106 FOB: Destination Period of Performance: 06/04/2018 to 09/29/2021				
1	ASPR-18-02838 -- Base period funds to Cue Health Inc for the development of a first-in-class reusable platform-based influenza in vitro diagnostic (IVD) test for in-home use Obligated Amount: \$14,000,000.00				14,000,000.00
2	Multiplex Respiratory Pathogen Cartridge (RSV, Corona Virus) Amount: \$15,849,178.00 (Option Line Item)				0.00
3	Supply Cue Cartridge and Reader for Influenza Natural History Studies Amount: \$151,000.00 (Option Line Item)				0.00

## **SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

### **B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

This contract will demonstrate the feasibility of the development of a first in class in-home molecular influenza diagnostic platform that is FDA cleared through 510K/CLIA Waived and will be ultimately approved for over the counter use.

The assay will be focused on the detection of both emerging infectious diseases as well as a multiplex typing/subtyping influenza assay for detection and differentiation of Influenza A and B and specific influenza A subtypes (H3N2 and H1N1). Cue's strategy for Influenza plans use of M1 as the target for Influenza A and NS1 for Influenza B.

The Cue program will support the acceleration of analytical performance, verification, validation, pre-clinical, clinical studies and FDA submissions (510k and OTC).

The diagnostic product is a cartridge reader for multiple uses, disposable test cartridges, sample collection devices, and a network enabled mobile device. The features of the mobile application allow an interventional component (telemedicine consultation) as well as both usage in detection and longitudinal monitoring of chronic diseases. This device is a platform approach for the in-home diagnostic that can be used for multiple purposes. The proposer is working on both Influenza, Zika, HIV, other targets.

The test is a nucleic acid amplification test (isothermal) along with ability to, depending on test type, use the following: reverse transcriptase, DNA polymerase/recombinase, magnetic particles conjugated with capture antibodies or proteins. Current predicted time to result is <25 minutes and the influenza diagnostic will utilize a lower nasal swab for sample collection.

### **B.2. TYPE OF CONTRACT AND ESTIMATED COST**

- a. This award is a COST REIMBURSEMENT (CR) type contract for Research and Development with a 20-month cost reimbursement Base Period. There is one 36-month Cost-Plus Fixed Fee (CPFF) option period that may or may not be exercised. If exercised, the option could run concurrently or in succession with a portion of the base. The total Period of Performance shall not to exceed five (5) years.

- b. The total estimated cost of the base period is **\$14,000,000**

The total estimated cost of the option period is **\$14,963,315**. The total fixed fee for the option period is **\$1,036,863**. The total estimated value of option period of the contract, CLINs 0002 and 0003, is **\$16,000,178**

The total estimated dollar value of this contract is **\$30,000,178**

**c. Base Period of Performance: June 4, 2018 through January 3, 2021**

<u>CLIN</u>	<u>Item Description</u>	<u>Estimated Cost</u>
0001	Cue Health Monitoring System with Cue Influenza Cartridge and Cue Health Mobile App/Professional App	<u>\$14,000,000</u>
<b>Total</b>		<u>\$14,000,000</u>

- d. Unless the Government exercises its option(s) pursuant to the option clause referenced in Section I, this contract consists only of the Base Period specified in the Statement of Work as defined in SECTIONS C and F, for the estimated cost set forth under B.2.of this contract.
- e. Pursuant to FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in Section I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform the option set forth in the Statement of Work in Section C and Attachment 8. If the Government exercises this option, notice must be given at least 30 days prior to the expiration date of this contract. Deliverables as set forth in Section F will commence on an agreed upon schedule if an option is exercised by the Government. The price of this contract will be increased as set forth in paragraph f, below.
- f. Upon exercise of the option the Government shall pay the Contractor on a cost-plus-fixed-fee basis for the work described in SECTION C of the contract and identified in the schedule below:

**Option Period of Performance: September 30, 2018 through September 29, 2021**

<u>CLIN</u>	<u>Item Description</u>	<u>Total Estimated Cost</u>	<u>Fixed Fee (7% for CLIN 0002 only)</u>	<u>Total Estimated Cost Plus Fixed Fee</u>
0002	Multiplex Respiratory Pathogen Cartridge (RSV, Corona Virus)	\$14,812,315	\$1,036,863	\$15,849,178
0003	Supply Cue Cartridge and Reader for Influenza Natural History Studies	\$151,000	\$0	\$151,000
<b>Total</b>		14,963,315	\$1,036,863	\$16,000,178

### B.3. ADVANCED UNDERSTANDINGS

1. **Export control notification:** Contractor is responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractor may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CFR Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CFR Parts 730-774).
2. **Persons-in-Plant:** With seven (7) days advanced notice to the Contractor, in writing from the Contracting Officer, the Government may place two (2) persons-in-plant in the Contractor's facility or in any subcontractor's portion of the facility in which the Contractor has ongoing work within the scope of this contract. The individuals shall be subject to the Contractor policies and procedures regarding security and facility access at all times while in the Contractor's facility.
3. **Subcontracts, Consultants Equipment and Materials:** Award of any fixed-price subcontract that exceeds \$250,000 or 5% of the total estimated cost of the contract, or any cost reimbursement, time and materials, or labor hour subcontracts or any equipment or material purchase for the contract shall require Contracting Officer Approval (COA). Supporting documentation required by FAR 52.244-2 must be submitted with the request. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract and consulting agreement shall be provided to the Contracting Officer within thirty (30) days.

#### Definitions:

**"Equipment"** means a tangible item that is functionally complete for its intended purpose, durable, nonexpendable, and needed for the performance of a contract. Equipment is not intended for sale, and does not ordinarily lose its identity or become a component part of another article when put into use. Equipment does not include material, real property, special test equipment or special tooling.

**"Durable"** means foreseeable use beyond the R&D contract.

**"Material"** is described as consumables. Consumables are goods that are capable of being consumed; that may be destroyed, dissipated, wasted, or spent.

NOTE: Cue Health, Inc. will be required to notify the Contracting Officer and keep a COA log that contains the SOW, Master Consulting Services Agreement, and any proposed resumes of key subcontractor personnel.

4. **File Audits:** All files may be audited by the US Government at any time in accordance with FAR 52.215-2, Audit and Records-Negotiation, during normal business hours, with a three (3) business day written notice.

- 5. Information Disclosure:** Disclosure of information/data received from the Government that is sensitive in nature, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

Notwithstanding the foregoing, such information/data shall not be deemed of a sensitive nature with respect to the Contractor for purposes of this contract if such information/data: (a) was already known to the Contractor; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to the Contractor; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to the information/data by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the Government that controls such information/data not to disclose such information/data to others; or (e) was independently discovered or developed by the Contractor, as evidenced by its written records, without the use of information/data belonging to the Government.

Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the Contractor shall first have given immediate notice to the Government and give the Government a reasonable opportunity to quash such order and/or to obtain a protective order requiring that the information/data of a sensitive nature that is the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued. The Government has the right to elect any and all remedies available to it in responding to any such order or similar legal document; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the information/data disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order; (b) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that all such information will be provided in advance to the Contracting Officer for review and reasonable measures shall be taken to assure confidential treatment of such information/data. Notwithstanding the foregoing, Contractor may disclose information/data sensitive to the Government if such disclosure is deemed by Contractor legal counsel to be required for purposes of complying with laws, rules or regulations of other governmental agencies, such as the Food and Drug Administration or the Securities and Exchange Commission. In the event of any such required disclosure, Contractor will notify the Contracting Officer in advance.

6. **Testing of Cue Health, Inc. IVD against Pandemic Strains:** The contractor shall, at the request of the COR/CO, make Cue diagnostic devices and test cartridges manufactured hereunder available to intergovernmental agencies to test cross-reactivity against new and emerging strains of pandemic respiratory strains (influenza, other respiratory diseases) should the need arise. Such testing will be conducted at no cost to the contractor other than prototyping and manufacturing of devices. Study results shall be shared with the contractor and all information will be kept confidential unless agreed upon by both parties.
7. **Phase Review Meeting:** It is anticipated that contractor shall prepare to presentation and briefing to COR/CO upon completion of WBS/IMS 1.1.3.5: Human Factors Usability Studies and Pilot Study with Lay Users Self-Testing. The phase review meeting will be gated to incorporate the go/no-go milestone set forth in Section F.2 below to proceed with further development of base period activities.

#### B.4. DIRECT COSTS

##### a. Items Unallowable Unless Otherwise Provided

Notwithstanding Clause 52.216-7, ALLOWABLE COST AND PAYMENT incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

- (1) Conferences and Meetings;
- (2) Food for Meals, Light Refreshments, and Beverages;
- (3) Promotional Items [*includes, but is not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees.*];
- (4) Acquisition, by purchase or lease, of any interest in real property;
- (5) Special rearrangement or alteration of facilities;
- (6) Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
- (7) Travel to attend general scientific meetings;
- (8) Reserved;
- (9) Accountable Government Property (defined as non-expendable personal property with an acquisition cost of \$3,000 or more) and "sensitive items" (defined as items of personal property (supplies and equipment that are highly desirable and easily converted to personal use)), regardless of acquisition value;
- (10) Printing Costs (as defined in the Government Printing and Binding Regulations; and
- (11) Overtime (premium) compensation.

##### b. Items requiring written Contracting Officer's Authorization prior to approval:

- 1) Entering into certain types of subcontract of arrangements (see above for specific obligations). Note that most consulting agreements require approval.
- 2) Foreign Travel (see below);
- 3) Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer, with a copy to the Contracting Officer's Representative (COR), at least six (6) weeks in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meetings, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provide; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.
- 4) Clinical Study Protocols- a draft must be submitted for review and feedback in advance of IRB submission.
- 5) Animal Study Protocols- a draft must be submitted for review and feedback in advance of IACUC submission.

## Travel Costs

- 1) All travel must follow GSA regulations including per-diem, cost of airfare, and expenses incurred.
- 2) **Foreign Travel:** Total expenditures for foreign travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed **\$0** without the prior written approval of the Contracting Officer.
- 3) The Contractor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.2 - Contracts with Commercial Organizations, Subsection 31.205-46, Travel Costs

In the event foreign travel is required, requests for foreign travel must be submitted at least four weeks in advance and shall contain the following:

- (a) meeting (s) and place(s) to be visited, with costs and dates;
- (b) name(s) and title(s) of Contractor personnel to travel and their functions in the contract project;
- (c) contract purposes to be served by the travel;
- (d) how travel of Contractor personnel will benefit and contribute to accomplishing the

- contract project, or will otherwise justify the expenditure of ASPR contract funds;
- (e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and
  - (f) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

## SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

### C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the detailed Statement of Work (SOW) attached to this contract as Attachment SOW (SECTION J-List of Attachments).

#### Statement of Work

The contractor will demonstrate the feasibility of the development of a first in class in-home molecular influenza diagnostic test and platform that is FDA cleared through 510K/CLIA Waived and ultimately approved for over the counter use.

The contractor shall conduct necessary activities required for a FDA 510K CLIA-Waived amendment submission and OTC submission by:

#### BASE PERIOD Tasks:

ACTIVITY
Assay Development
Clinical Studies 510k/CLIA Waived and OTC
Regulatory Submissions
Bioproduction Manufacturing
Cartridge Manufacturing

#### OPTION PERIOD Tasks

ACTIVITY
Multiplex Assay Development
Clinical Studies 510k/CLIA Waived and OTC
Regulatory Submissions
Bioproduction Manufacturing
Cartridge Manufacturing (not to exceed 5,000 cartridges and 100 readers)

### C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Helpful Resources."

## **a. Technical Reports**

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract:

### **1. Monthly Progress Report**

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of full calendar months.

The Contractor shall submit a Monthly Progress Report according to the dates set forth in ARTICLE F.2. of this contract. The format should include:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission; The progress report shall conform to the requirements set forth in the DELIVERABLES Article in SECTION F of this contract.

- SECTION I – An introduction covering the purpose and scope of the contract effort
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes). A standing organizational chart is to be included in this section.
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts. Any revisions to the Timeline, Work Breakdown Structure (WBS) and Risk Assessment.

A Monthly Progress Report will not be required in the same month that the Annual Technical Progress Report is submitted.

The first report shall be due the **15th calendar day** after completion of the first full Calendar month and portion thereof of performance. Thereafter, reports shall be due on or before the 15th calendar day following each reporting period.

## **2. Annual Progress Report**

This report shall include a summation of the results of the entire contract work for the period covered. An Annual Technical Progress Report will not be required for the period when the Final Technical Progress Report is due. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due.

The first Annual Progress Report shall be submitted in accordance with the date set forth in Section F of this contract. Each Annual Progress Report shall include:

A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission; The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating, and managing subcontractor performance; regulatory compliance audits, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;
- SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year's performance period to include an updated Gantt Chart.

Contractor also should include the following in the Annual Progress Report:

- a. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and
- b. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

The first report shall cover the period June **4, 2018** through **May 31, 2019** of this contract and shall be due within **30 Calendar days** after the Anniversary Date of the Contract.

### **3. Draft Final Technical Progress Report and Final Technical Progress Report**

A Draft Final Report will be submitted to the Contracting Officer's Representative for review and comment at least 45 days prior to the contract completion date. Within 15 days of receipt, the Contracting Officer's Representative will provide the Contractor written comments on the Draft Final Report.

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Technical Progress Report will not be required for the period when the Final Technical Progress Report is due. The Draft Final Technical Progress Report and the Final Technical Progress Report shall be submitted in accordance with the dates set forth in ARTICLE F.2. of this contract. The report shall conform to the following format:

- a. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, e-mail address and submission date.
- b. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.
- c. SECTION II: RESULTS - A detailed description of the work performed related to the Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

**Draft Technical Progress Report:** The Contractor is required to submit the Draft Final Technical Progress Report to the Contracting Officer's Representative and Contracting Officer. This report is due 45 calendar days before the completion date of the contract. The Contracting Officer's Representative and Contracting Officer will review the Draft Final

Technical Progress Report and provide the Contractor with comments within 15 Calendar days after receipt.

Final Technical Progress Report: The Contractor shall incorporate all BARDA comments into the Final Technical Progress Report. The Contractor will deliver the final version of the Final Technical Progress Report 30 Calendar days post technical period of performance.

#### **4. Summary of Salient Results**

The Contractor shall submit, with the Final Report, a summary (not to exceed 400 words) of salient results achieved during the performance of the contract.

#### **5. Copies of FDA/ Regulatory Agency Correspondence and Meeting Summaries**

- a. The Contractor shall forward the initial draft minutes and final draft minutes of any formal meeting with the FDA and other regulatory agencies to the COR.
- b. The Contractor shall forward the final draft minutes of any informal meeting with the FDA and other regulatory agencies to the COR.
- c. The Contractor shall forward the dates and times of any meeting with the FDA and other regulatory agencies to the COR and make arrangements for appropriate COR and staff to attend the meetings.
- d. The Contractor shall provide the COR the opportunity to review and comment upon any draft documents, including draft pre-submission packages, and meeting requests, to be submitted to the FDA or other regulatory agency. The Contractor shall provide the COR with five (5) business days in which to review and provide comments back to the Contractor.

#### **6. FDA/Regulatory Agency Submissions**

The Contractor shall provide COR 14 calendar days, the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final".

Administrative submissions (correspondence that will not be used to support a regulatory strategy position) may be supplied to the COR/CO at the time of FDA submission.

#### **7. Other Reports/Deliverables**

- a. **Study/Experiment/Test Plans/Protocols/Batch Records** - The Contractor shall submit (14 days in advance) all study/experiment/test plans, designs, and protocols for review and feedback. COR/CO reserve the right to make any suggestions and requests for clarification prior to conduct of said activity.
- b. The Contractor shall forward Standard Operating Procedures (SOPs) pertinent to the work hereunder upon request from Contracting Officer's Representative

- /Contracting Officer.
- c. The Contractor shall provide upon request animal study and/or other technology packages developed under this contract. Packages shall include complete protocols and critical reagents for animal models developed and/or improved with contract funding.
  - d. The Contractor shall provide upon request raw data and/or specific analysis of data first produced with USG funds.
  - e. **Meeting Minutes** - The Contractor shall provide an electronic copy of conference call meeting minutes/summaries to the Contracting Officer's Representative and Contracting Officer within five (5) business days after the conference call is held.
  - f. **Written request for modifications to current product design and specifications** - COR/CO must be notified of any major modifications or changes to materials/reagents/components used, current product design and/or specifications requiring a change in any Certificate of Analysis (COA).
  - g. **Audit Reports** – Report is required whenever an audit pertinent to the work hereunder occurs.
  - h. **Reporting of Financial Conflict of Interest (FCOI)** - All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in electronic format. Thereafter, reports shall be due in accordance with the regulatory compliance requirements in 45 CFR Part 94. 45 CFR Part 94 is available at: <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>. See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

### C.3. SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract. Reports and documentation submitted to the Contracting Officer shall be sent to the following email and/or address:

HHS/ASPR/AMCG  
ATTN, S. Kyle Roberts  
Contracting Officer  
US DEPT OF HEALTH & HUMAN SERVICES  
ASST SEC OF PREPAREDNESS & RESPONSE  
ACQ MANAGEMENT, CONTRACTS, & GRANTS  
#21E02 O'NEILL HOUSE OFFICE BUILDING  
Washington DC 20515 Email: [kyle.roberts@hhs.gov](mailto:kyle.roberts@hhs.gov)

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

The Government agrees that the background inventions listed at Attachment 8 to this contract shall not be considered "Subject Inventions" under FAR 52.227-11.

#### **C.4. MONTHLY CONFERENCE CALLS**

Two conference calls between the Contracting Officer's Representative and the Contractor shall occur every month, or as directed by the Contracting Officer's Representative. During these calls the Principal Investigator/Main Point of Contact will discuss the activities performed and deliverables achieved during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The first reporting period consists of the first half month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each half calendar month. The Contractor may choose to include other key personnel on the conference call to give detailed updates on specific projects or the Contracting Officer may request this.

#### **C.5. PROJECT MEETINGS**

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may include face-to-face meetings with AMCG/BARDA in Washington, D.C. and at work sites of the Contractor. Such meetings may include, but are not limited to, meetings of the Contractor to discuss study designs, site visits to the Contractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. Subject to the data rights provisions in this contract and other appropriate confidentiality protections, the Contractor must provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Contracting Officer's Representative in order to facilitate review of contract activities.

#### **C.6. IN-PROCESS-REVIEW**

At its discretion, the Government may conduct an In-Process-Review (IPR) to evaluate whether to continue activities covered by the contract. Contractor shall provide a presentation detailing technical progress made towards completion of milestones following a prescribed template provided by the Government at an agreed upon date. The IPR will typically be conducted at DHHS facilities in Washington, DC. The contractor will be notified by the Government of its intention to hold an IPR at least 30 calendar days prior to the scheduled IPR Presentation.

- Contractor shall provide final presentation 10 business days prior to each IPR Presentation.

- Contractor shall submit written justification of progress towards satisfying success criteria.
- If draft is provided prior to the final presentation submission, the Government will provide a written or verbal response, as appropriate.

#### **C.7. SITE VISITS AND INSPECTIONS**

At the discretion of the USG and with seven (7) business days' notice to the Contractor, the USG reserves the right to conduct site visits and inspections on contractor and subcontractors on an as needed basis.

## SECTION D - PACKAGING, MARKING AND SHIPPING

### Packaging

As required, packaging and labeling of products developed under this contract shall be consistent with the FDA guidance on regulatory requirements for medical devices – i.e., applicable provisions under Parts of Title 21 CFR Part 801, 809, 812, 820, 830, 1010.

### Shipping

Shipment of deliverables will be at the direction of the Contracting Officer.

### Report Deliverables

All reports and deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

Unless otherwise specified by the Contracting Officer, delivery of reports to be furnished to the Government under this contract (including invoices) shall be delivered to the Contracting Officer electronically along with a concurrent email notification to the Contracting Officer and COR (as defined in SECTION G, CONTRACT ADMINISTRATION) summarizing delivery as follows:

#### Mailing Address

Justin Yang  
Contracting Officer's Representative  
DHHS/OS/ASPR/BARDA  
O'Neill House Office Building  
#21E09  
Washington, D.C. 20515

#### E-Mail Address

Justin.yang@hhs.gov

#### Mailing Address

S. Kyle Roberts  
Contracting Officer  
DHHS/OS/ASPR/AMCG  
O'Neill House Office Building  
#21E02  
Washington, D.C. 20515

#### E-Mail Address

Kyle.Roberts@hhs.gov

## **SECTION E - INSPECTION AND ACCEPTANCE**

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this contract.
- b. For the purpose of this SECTION, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer.
- c. For report deliverables, inspection and acceptance will be performed at:

Office of Acquisition Management, Contracts, and Grants (AMCG)  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services  
330 Independence Avenue, S.W., Room G644  
Washington, D.C. 20201

- d. For option items, inspection and acceptance will be performed at the specified delivery site.
- e. FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address:  
<http://www.acquisition.gov>.

FAR Clause **52.246-9, Inspection of Research and Development (Short Form)(Apr 1984)**.

## SECTION F - DELIVERIES OR PERFORMANCE

### F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall be from **June 4, 2018 through January 3, 2021** for the base period.
- b. If the Options are exercised, they may run concurrently with the base period for various time lengths but shall not exceed the 60 months.

### F.2. DELIVERABLES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

#### Base Period

WBS	Description	Quantity/ Electronic	Schedule
BARDA reports and correspondence			
N/A	<b>Integrated Product Development Plan (IPDP):</b> BARDA will receive a detailed work plan with phasing, key project activities, milestones and go/no go decisions.	1 - COR 1 - CO	Submitted 30 days from contract start date for approval, to include Design and Development Plan with decision gates. Offeror shall submit an updated IPDP when changes are necessary and after each Phase.
N/A	<b>Monthly technical reports:</b> summaries of activities during the previous calendar month, milestones achieved, issues resolved, issues outstanding, planned activities during current month	1 - COR 1 - CO	Due on 15th of each month, except in months when quarterly report or annual reports are due or when project stage-gates occur
N/A	<b>Regulatory Plan:</b> BARDA will receive a detailed regulatory plan submitted by contractor summarizing activities, milestones, and planned activities	1 - COR 1 - CO	Due within 60 days from contract start
N/A	<b>Risk Management Plan for the overall program</b>	1 - COR 1 - CO	Submitted 30 days from contract start date for approval, and updated quarterly or as necessary. This plan must reference relevant key milestones and activities where appropriate.

WBS	Description	Quantity/ Electronic	Schedule
N/A	<b>Annual report which includes:</b> <ul style="list-style-type: none"> <li>- Summary of activities during the year</li> <li>- Milestones achieved</li> <li>- Issues resolved and outstanding</li> <li>- Overall project and product risk profile highlighting major risks addressed and remaining</li> <li>- Planned activity for the following year</li> <li>- Actual and expected revisions to WBS and IPDP</li> </ul>	1 - COR 1 - CO	30 calendar days after the end of the 12 month period which ends on May 31, 2019
BARDA will receive 1 Annual progress report per annum, plus 1 draft final and 1 final written progress report. Each report shall include a section reporting deviations from the IPDP and/or WBS.			
N/A	<b>Draft final report</b> which includes: <ul style="list-style-type: none"> <li>- Summary of product design and performance specifications</li> <li>- Summary of product clinical performance</li> <li>- Overview of 510(k) submission process and status</li> <li>- Overview of manufacturing and logistics capabilities to deliver the product to market</li> </ul>	1 - COR 1 - CO	45 calendar days before the contract expiration date.
N/A	<b>Final report</b> which includes: see above "Draft final report"	1 - COR 1 - CO	Up to but no later than 30 calendar days after contract expiration date.
N/A	<b>All FDA/ Regulatory Correspondence, Meeting Summaries, and any material submitted to FDA</b>	1 - COR 1 - CO	Within 5 business days of each meeting for Contractor's minutes and upon receipt of minutes from FDA / regulatory agency.
N/A	<b>End-of-phase review meeting and Integrated Product Review meeting presentations</b>	1 - COR 1 - CO	Submitted to BARDA 14 days prior to the meeting.
Other reports and deliverables (appended to monthly technical progress reports):			
N/A	<b>Quality Plan and Quality Systems Requirements Document</b> <b>ISO13485 certified Quality Management systems plan</b>	1 - COR 1 - CO	Submitted 30 days from contract start date for review
N/A	<b>Software Development Plan and Requirements Document</b> <ul style="list-style-type: none"> <li>• System Requirements</li> <li>• Instrument Product Requirements</li> <li>• Cartridge Product Requirements</li> <li>• Software Requirements</li> <li>• FMEA and/or HHA</li> </ul>	1 - COR 1 - CO	Submitted 30 days from contract start date for review.
N/A	<b>Study Designs and Protocols</b> – See contract.	1 - COR 1 - CO	For BARDA review prior to the commencement of any clinical study

WBS	Description	Quantity/ Electronic	Schedule
N/A	<b>Data</b> – See contract.	1 - COR 1 - CO	At the request of the COR.
N/A	<b>Meeting minutes</b> – See contract	1 - COR 1 - CO	Within 5 business days after a conference call or meeting.
N/A	<b>Written request for modifications</b> and contract officer approvals	1 - CO	
	<b>Audit reports</b>	1 - COR 1 - CO	Within 30 Calendar days of an audit.
	<b>Notification of Delays</b>	1- CO	Notify CO if > 10 business day delay or shift in timeline of key gates
	<b>Invention report and annual utilization report</b> (See Article C.3.)	1 - COR 1 - CO	Due on or before the 30th of the month following each anniversary date of the contract.
	<b>Final invention report</b> (See Article C.3.)	1 - COR 1 – CO	Due on or before contract expiration date.

Feasibility (part 1)			
WBS	Task/Milestone	Quantity / Electronic	Success Criteria and Deliverable
1.1.2	<b>Assay Development</b>	1 - COR 1 - CO	<p><b>Test protocols:</b> All test protocols in relation to Assay Development must be provided to COR/CO within 14 days of study start.</p> <p><b>Study Reports:</b> Study reports must be provided to COR/CO for review and feedback within 7 days of report completion.</p> <p><b>Deliverables:</b></p> <ul style="list-style-type: none"> <li>• Report on optimization of triplex primer set, formulation optimization of buffer and lyophilization recipe, mixing optimization, and valving optimization.</li> <li>• Mucin matrix study report</li> <li>• LOD study report</li> <li>• Assay compatibility and fluid properties report</li> <li>• Intra/Inter assay precision and lot-to-lot agreement report</li> <li>• Analytical Reactivity Study Report</li> <li>• Analytical Specificity &amp; potential interferents Study Report</li> <li>• Specimen Stability Study Report</li> <li>• Flex/Guard-band study report</li> <li>• Cartridge stability study report</li> <li>• Cartridge shipping stability and shipping stress study report</li> </ul> <p><b>Go/No-Go Milestone:</b> Analytical performance studies including compliance with acceptance criteria of demonstrated long term stability success and meets all pre-defined requirements as agreed upon between BARDA and contractor.</p>

WBS	Task/Milestone	Quantity / Electronic	Success Criteria and Deliverable
1.1.3	<b>Clinical Studies</b>	1 - COR 1 - CO	<p><b>Interim feasibility pilot studies report:</b> prior to conduct of studies in support of 510k clearance for OTC claim, pilot study with lay users self-collecting their nasal sample using the Cue sample wand and self-testing nasal sample must be accepted by BARDA.</p> <p><b>Deliverables:</b></p> <ul style="list-style-type: none"> <li>- Human Factors/Usability Studies</li> <li>- Pilot Studies with Lay Users Self Testing</li> <li>- BARDA reviewed Clinical Study Protocols, Statistical Analysis Plans, Data Management Plans, eDatabase (Clinical database and eCRF)</li> <li>- Clinical Study Site, Central Lab Qualification and Selection for Method Comparison, Reproducibility/Repeatability, and Samples at LoD Studies</li> <li>- Clinical Study Site Contracts</li> <li>- Institutional Review Board (IRB) Submissions and Approvals of Each Clinical Validation Protocol</li> <li>- Clinical Study Materials</li> <li>- Clinical Site Initiation</li> <li>- Clinical Sites Reproducibility/Repeatability Study Conducted and Reported</li> <li>- Clinical Sites Testing of Samples with Influenza Concentration near the LoD Conducted and Reported</li> </ul> <p><b>GO/NO Go Acceptance Criteria:</b> Government acceptance of above deliverables are required prior to moving to OTC/POC CLIA Waived Method Comparison Studies. Phase review meeting (IPR) to be conducted prior to undertaking of further clinical studies (Phase Review Meeting). It is understood that BARDA and contractor will predefine and agree on success criteria of pilot clinical studies during the protocol development process prior to the clinical study start.</p> <ul style="list-style-type: none"> <li>- OTC and POC/CLIA Waived Method Comparison Studies</li> <li>- BIMO Inspections</li> </ul>
1.1.4	<b>Regulatory Submissions</b>	1 - COR 1 - CO	<b>See C.2. Reporting Requirements</b>

WBS	Task/Milestone	Quantity / Electronic	Success Criteria and Deliverable
1.1.5	<b>Bioproduction Manufacturing</b>	1 - COR 1 - CO	<b>Deliverables:</b> <ul style="list-style-type: none"> <li>Enzyme Process Transfer and Validation report</li> <li>Lyophilization Process Development and Verification (3 pre-production lots of enzyme passing QC specifications)</li> <li>Lyophilization Formulation Lock and Design Freeze – Completion of transfer protocol</li> <li>Lyophilization Process Transfer and Validation – Completion of lyophilization validation report</li> <li>Bioproduction scale up for post 510k commercialization (commercial batch scale feasibility and scale-up) completion report</li> </ul>
1.1.6	<b>Cartridge Manufacturing</b>  Includes fabrication of manufacturing systems, validation of cartridge automation line and manufacture of Cue Influenza Cartridges for analytical and clinical validation. The systems that encompass the automation line for cartridge manufacturing are: 1500- PCB Processing Machine, 1501- Fluidic Subassembly Machine, 1502- Flavoring Machine, 1503- Finishing Machine, 1504- Cartridge Printing Machine, 1505- Cartridge Pouching Machine, 1506- Lyophilized Bead Dispense System, 1507- Fluid Wand Assembly Machine, 1701- Fluidic/PCB Assembly Machine, 1708- Fluidic Pre- Processing Machine and 1709- Wax-Dispense System.  Deliverables generated under this WBS shall follow appropriate design control documentation as required under Quality System Regulations 21 CFR 820.	1 - COR 1 - CO	<b>Deliverables:</b> <ul style="list-style-type: none"> <li>System level drawings for each automation system/machine</li> <li>System level specifications for each automation machine</li> <li>Documented project approvals for each system</li> <li>Design review and approval for each system</li> <li>Validation for dry room performance</li> <li>Fabrication of systems</li> <li>System debug completion</li> <li>Optimization and final debug report</li> <li>Documentation accepted by BARDA for each system</li> <li>Validation protocols for each system</li> <li>Validation IQ/OQ/PQ completed report and approval</li> <li>Manufacture of 3 lots of Cue Influenza Cartridges for analytical and clinical validation</li> <li>Manufacture scale up to meet cartridge sales post FDA 510(k) clearance</li> <li>Maintenance of ISO13485 certification, quality audits, instrument calibrations, QA and release batch records</li> <li>ERP, purchasing, supply chain and inventory management, production/quality team coordination</li> <li>Develop testing systems for iOS consumer and professional apps, validation of software</li> </ul>

**Option 1/CLIN 0002 – Cue Health Monitoring System with Cue Multiplex Respiratory Pathogen Cartridge and Cue Health Mobile App**

WBS	Description	Quantity / Electronic	Schedule
BARDA reports and correspondence			
N/A	<b>Integrated Product Development Plan (IPDP):</b> BARDA will receive a detailed work plan with phasing, key project activities, milestones and go/no go decisions.	1 - COR	Submitted 30 days from contract start date for approval, to include Design and Development Plan with decision gates. Offeror shall submit an updated IPDP when changes are necessary and after each Phase.
N/A	<b>Monthly technical reports:</b> summaries of activities during the previous calendar month, milestones achieved, issues resolved, issues outstanding, planned activities during current month	1 - COR 1 - CO	Due on 15th of each month, except in months when quarterly report or annual reports are due or when project stage-gates occur
N/A	<b>Risk Management Plan</b>	1 - COR 1 - CO	Submitted 30 days from contract start date for approval, and updated quarterly or as necessary. This plan must reference relevant key milestones and activities where appropriate.
N/A	<b>Annual report which includes:</b> <ul style="list-style-type: none"> <li>- Summary of activities during the year</li> <li>- Milestones achieved</li> <li>- Issues resolved and outstanding</li> <li>- Overall project and product risk profile highlighting major risks addressed and remaining</li> <li>- Planned activity for the following year</li> <li>- Actual and expected revisions to WBS and IPDP</li> </ul>	1 - COR 1 - CO	30 calendar days after the end of the 12 month period beginning on the option exercise date
BARDA will receive 1 Annual progress report per annum, plus 1 draft final and 1 final written progress report. Each report shall include a section reporting deviations from the IPDP and/or WBS.			
N/A	<b>Draft final report</b> which includes: <ul style="list-style-type: none"> <li>- Summary of product design and performance specifications</li> <li>- Summary of product clinical performance</li> <li>- Overview of 510(k) submission process and status</li> <li>- Overview of manufacturing and logistics capabilities to deliver the product to market</li> </ul>	1 - COR 1 - CO	45 calendar days before the contract expiration date.
N/A	<b>Final report</b> which includes: see above "Draft final report"	1 - COR 1/1 - CO	Up to but no later than 30 calendar days after contract expiration date.
N/A	<b>All FDA/ Regulatory Correspondence, Meeting Summaries, and any material submitted to FDA</b>	1 - COR 1 – CO	Within 5 business days of each meeting for Contractor's minutes and upon receipt of minutes from FDA / regulatory agency.

WBS	Description	Quantity / Electronic	Schedule
N/A	<b>End-of-phase review meeting and Integrated Product Review meeting presentations</b>	1 - COR 1 – CO	Submitted to BARDA 14 days prior to the meeting.
Other reports and deliverables (appended to monthly technical progress reports):			
N/A	<b>Software Development Plan and Requirements Document</b>	1 - COR 1 – CO	Submitted 30 days from contract start date for review.
N/A	<b>Study Designs and Protocols</b> – See Article XXX.	1 - COR	For BARDA review prior to the commencement of any clinical study
N/A	<b>Data</b> – See Article XXX.	1 - COR	At the request of the COR.
N/A	<b>Meeting minutes</b> – See Article XXX.	1 - COR	Within 5 business days after a conference call or meeting.
N/A	<b>Written request for modifications</b> and contract officer approvals for equipment/materials expenditures > \$1500	1 - CO	
	<b>Audit reports</b>	1 - COR 1 - CO	Within 30 Calendar days of an audit.
	<b>Notification of Delays</b>	1- CO	Notify CO if > 10 business day delay or shift in timeline of key gates
	<b>Invention report and annual utilization report</b> (See Article C.3.)	1 - COR 1 - CO	Due on or before the 30th of the month following each anniversary date of the contract.
	<b>Final invention report</b> (See Article C.3.)	1 - COR 1 – CO	Due on or before contract expiration date.

Option 1			
WBS	Task/Milestone	Quantity / Electronic	Success Criteria and Deliverable
1.2.2	<b>Multiplex Respiratory Pathogen Assay Development</b>	1 - COR 1 - CO	<ul style="list-style-type: none"> <li>• <b>Off-cartridge assay feasibility and cartridge development feasibility report</b></li> <li>• <b>Design verification studies and reporting</b></li> <li>• <b>Analytical performance validation study report</b></li> </ul> <b>Go/No-Go criteria to be agreed upon prior to exercise of option</b>
1.1.3	<b>Clinical Studies</b>	1 - COR 1 - CO	<p>Pre-submission to FDA and FDA feedback: prior to conduct of studies in support of 510k clearance for OTC claim, Cue will engage the FDA in addressing the clinical plan and IUO labelling</p> <p>Deliverables:</p> <ul style="list-style-type: none"> <li>- Vendor Selection and Engagement</li> <li>- Human Factors/Usability Studies</li> <li>- Pilot Studies with Lay Users Self Testing</li> <li>- Clinical Study Protocols, Statistical Analysis Plans, Data Management Plans, eDatabase</li> <li>- Clinical Study Site, Central Lab Qualification and Selection for Method Comparison, Reproducibility/Repeatability, and Samples at LoD Studies</li> <li>- Clinical Study Site Contracts</li> <li>- Institutional Review Board (IRB) Submissions and Approvals of Each Clinical Validation Protocol</li> <li>- Clinical Study Materials</li> <li>- Clinical Site Initiation</li> <li>- Clinical Sites Reproducibility/Repeatability Study Conducted and Reported</li> <li>- Clinical Sites Testing of Samples with Respiratory Pathogen Concentration near the LoD Conducted and Reported</li> <li>- OTC and POC/CLIA Waived Method Comparison Studies</li> <li>- BIMO Inspections</li> <li>- Go/No-Go criteria to be agreed upon prior to exercise of option</li> </ul>
1.1.4	<b>Regulatory Submissions</b>	0/1 - COR 0/1 - CO	See C.2. Reporting Requirements

WBS	Task/Milestone	Quantity / Electronic	Success Criteria and Deliverable
1.1.5	<b>Bioproduction Manufacturing</b>	0/1 - COR 0/1 - CO	<b>Deliverables:</b> <ul style="list-style-type: none"> <li>Enzyme Process Transfer and Validation report</li> <li>Lyophilization Process Development and Verification (3 pre-production lots of enzyme passing QC specifications)</li> <li>Lyophilization Formulation Lock and Design Freeze – Completion of transfer protocol</li> <li>Lyophilization Process Transfer and Validation – Completion of lyophilization validation report</li> <li>Bioproduction scale up for post 510k commercialization (commercial batch scale feasibility and scale-up) completion report</li> </ul>
1.1.6	<b>Cartridge Manufacturing</b>  Includes fabrication of manufacturing systems, validation of cartridge automation line and manufacture of Cue Multiplex Respiratory Pathogen Cartridges for analytical and clinical validation. The systems that encompass the automation line for cartridge manufacturing are: 1500- PCB Processing Machine, 1501- Fluidic Subassembly Machine, 1502- Flavoring Machine, 1503- Finishing Machine, 1504- Cartridge Printing Machine, 1505- Cartridge Pouching Machine, 1506- Lyophilized Bead Dispense System, 1507- Fluid Wand Assembly Machine, 1701- Fluidic/PCB Assembly Machine, 1708- Fluidic Pre- Processing Machine and 1709- Wax-Dispense System  <b>Deliverables generated under this WBS shall follow appropriate design control documentation as required under Quality System Regulations 21 CFR 820.</b>	0/1 - COR 0/1 - CO	<b>Deliverables:</b> <ul style="list-style-type: none"> <li>System level drawings for each automation system/machine</li> <li>System level specifications for each automation machine</li> <li>Documented project approvals for each system</li> <li>Design review and approval for each system</li> <li>Validation for dry room performance</li> <li>Fabrication of systems</li> <li>System debug completion</li> <li>Optimization and final debug report</li> <li>Documentation accepted by BARDA for each system</li> <li>Validation protocols for each system</li> <li>Validation IQ/OQ/PQ completed report and approval</li> <li>Manufacture of 3 lots of Cue Multiplex Respiratory Pathogen Cartridges for analytical and clinical validation</li> <li>Manufacture scale up to meet cartridge sales post FDA 510(k) clearance</li> <li>Maintenance of ISO13485 certification, quality audits, instrument calibrations, QA and release batch records</li> <li>ERP, purchasing, supply chain and inventory management, production/quality team coordination</li> <li>Develop testing systems for iOS consumer and professional apps, validation of software</li> </ul>

**CLIN 0003 – Option 2:**

WBS	Description	Quantity/ Paper / Electronic	Schedule
2.1	<b>Provide up to 20 Cue Influenza Readers and 5,000 test cartridges for HHS sponsored observational clinical studies</b>	0/1 - COR	Timing of the delivery will be in accordance to the execution of the Option + 60 days. Cue will provide fully functional and released per ISO/GMP standards 20 Cue Diagnostic Readers and up to 5,000 test cartridges, shipped within the United States at the request of the COR.

The items specified in SOW will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified in Section F.

**F.3. REPORTING REQUIREMENTS**

All reports required herein shall be submitted in electronic format.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Helpful Resources."

Item Description	Delivery Date	Deliver To
<i>Initial Project Management Deliverables</i>		
<i>Routine or Monthly Deliverables</i>		
<b>1. Technical Progress Report</b> in the format requested by the Contracting Officer describing project progress over the previous month	The 15 <sup>th</sup> of each month of Contract performance	CO and COR via e-mail. Additionally, email invoices to <a href="mailto:PSC_Invoices@psc.hhs.gov">PSC_Invoices@psc.hhs.gov</a>
<b>2. Integrated Master Schedule</b> in MS excel and .xml export	The 15 <sup>th</sup> of each month of Contract performance	
<b>3. Monthly Conference Call</b>	Proposed agenda 2 days prior to call each conference call	

Item Description	Delivery Date	Deliver To
<b>4. Quarterly Site Visit Minutes</b> for face-to-face meetings at Recipient or BARDA location	Within 10 days following each site visit	
<b>5. Monthly Invoices</b>	Within 60 days of the end of each month	
<b>6. Weekly Clinical Report during Active Enrollment Periods.</b> Format TBD	The Monday following the week being reported	COR via e-mail
<b>7. Clinical Site Enrollment Reporting and Updates</b> to support the BARDA Clinical Trial Database	The 15 <sup>th</sup> of each month of Contract performance when clinical trials are active	Direct transfer to a secure data capture system (BARDA Tracking Tool)
<i>Periodic or As-Necessary Deliverables</i>		
<b>1. Study Protocols</b> for each non-clinical or clinical trial	No later than 14 calendar days before submission to the FDA*	CO and COR via e-mail and, if requested, CD-ROM
<b>2. Study Reports</b> for each non-clinical or clinical trial	No later than 14 calendar days before submission to the FDA*	
<b>3. Manufacturing Campaign Reports</b> for contract funded material	No later than 14 calendar days before submission to the FDA*	
<b>4. Technical Documents</b> from contract funded activities such as Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis	Within 10 days upon request by CO/COR or 14 calendar days prior to submission to FDA*	
<b>5. In-Process Review</b> . Annual or event driven review of program	No later than 10 days before Milestone Review Meeting	
<b>6. Incident Report</b> for any critical programmatic concerns, risks or potential risks	Within two business days of incident	
<b>7. QA Audit Reports</b> including findings, results and next steps. BARDA reserves the right to participate in	Within 5 business days of report completion	
<b>8. Quality Agreements with Subcontractors.</b>	Within 10 calendar days upon request by CO/COR	

<b>Item Description</b>	<b>Delivery Date</b>	<b>Deliver To</b>
<b>9. Formal FDA Submissions</b> of any kind pertaining to the scope of the project as necessary during Contract performance	No later than 14 calendar days before submission to the FDA* BARDA will coordinate with Contractor for reviewing BLA sections	
<b>10. Memo with Date and Time of Scheduled Meetings with FDA.</b> BARDA reserves the right to attend FDA meetings relevant to contract funded activities	As soon as possible after scheduling	
<b>11. Communications from FDA</b> related to contract funded activities	Within 2 business days of receipt from FDA	
<b>12. Minutes for Formal Meetings with FDA</b>	Within 5 business days of receipt from FDA	
<b>13. Raw Data and Analysis Pertaining to Scope of the Project First Produced Using USG Funds</b>	Within a reasonable time after request	CO via electronic delivery
<b>14. Regulatory Strategies Pertaining to Scope of the Project</b>	Within a reasonable time after request	CO via electronic delivery
<b>15. Draft Final Report</b>	No later than 45 days prior to contract expiration	CO and COR via e-mail
<b>16. Final Report</b>	No later than 30 calendar days after contract period of performance expiration	CO and COR via e-mail
<b>17. Publications/Presentations</b>	No later than 30 calendar days before submission for publications and 15 calendar days for presentations	CO and COR via e-mail

#### **F.4. CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address:

<http://www.acquisition.gov/comp/far/index.html> .

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

**52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).**

**52.242-17, Government Delay of Work (APRIL 1984)**

**52.247-35, F.O.B. Destination Within Consignees Premises (APRIL 1984).**

**SECTION G - CONTRACT ADMINISTRATION DATA**

**G.1. CONTRACTING OFFICER**

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

S. Kyle Roberts, Contracting Officer  
HHS/OS/ASPR/AMCG  
O'Neill House Office Building  
#21E02  
Washington, D.C. 20515  
E-mail: [Kyle.Roberts@hhs.gov](mailto:Kyle.Roberts@hhs.gov).

- 1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.
- 2) The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.
- 3) No information, which may be received from any person employed by the US Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract, unless it is information which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer.
- 4) The Government may unilaterally change its CO designation.

**G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)**

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

Justin Yang  
Contracting Officer's Representative (COR)  
Biomedical Advanced Research and Development Authority (BARDA)

Office of the Assistant Secretary for Preparedness and Response  
Department of Health and Human Services

The COR is responsible for:

- 1) Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
- 2) Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;
- 3) Performing technical evaluation as required;
- 4) Performing technical inspections and acceptances required by this contract; and
- 5) Assisting in the resolution of technical problems encountered during performance.

The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance. The Contractor is advised to review Federal Acquisition Regulation ("FAR") Clause 52.243-2 (Changes-Cost reimbursement contracts Alternative V), which is incorporated by reference into this contract.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract. The Government may unilaterally change its COR designation.

### **G.3. INVOICE SUBMISSION/CONTRACT FINANCIAL REPORT**

- 1) Financial reports on the attached Financial Report of Individual Project/Contract (see Attachment 3) shall be submitted by the Contractor in accordance with the instructions for completing this form, which accompany the form, in an electronic copy, not later than the 15th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are discussed in paragraph 5, below. Subsequent changes and/or additions in the line entries shall be made in writing.
- 2) Unless otherwise stated in that part of the instructions for completing this form, entitled "PREPARATION INSTRUCTIONS," (see Attachment 3) all columns A through J, shall be completed for each report submitted.
- 3) The first financial report shall cover the period consisting of the first full calendar month following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a **Monthly** basis. If the contractor fails to submit timely financial reports and invoices

or is delinquent on submission of financial reports by an excess of 90 Calendar days, a "Stop Work Order" may be issued by the Government, until the delay is resolved.

- 4) The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.
- 5) The listing of expenditure categories to be reported is incorporated within the Attachment entitled, "Financial Report of Individual Project/Contract," located in SECTION J and made a part of this contract.

#### **G.4. INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING**

- 1) The billing address that should be shown on the invoice is the same as defined above in Section G of this contract.
- 2) The Contractor shall submit an electronic copy of contract **Monthly invoices/financial reports** to the Contracting Officer as defined above, in Section G of this contract.
- 3) Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting made a part of the contract in Section J (See Attachments 1, 2, 3).
- 4) Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.
- 5) The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base segment or any option segment(s) (See estimated costs under B.2. and B.3., of the contract) and the reasons for the variance. Also refer to the requirements of the Limitation of Cost FAR 52.232-20 clause in the contract.
- 6) All invoice submissions shall be in accordance with FAR Clause 52.232-25(a)(3) in Section I of this contract.
- 7) The Contractor shall reference any applicable Contractor Officer Authority (COA) numbers when requesting reimbursement on the invoice.

#### **G.5. REIMBURSEMENT OF COST**

- 1) The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with the clause entitled Allowable Cost and Payment in Section I, Contract Clauses, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

- a) All direct materials and supplies that are used in the performing of the work provided for under the contract, including those purchased for subcontracts and purchase orders.
- b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.
- c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.
- d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following and the restrictions in Section B:
  - (i) Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).
  - (ii) Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.
  - (iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they comply with FAR 31.2.
  - (iv) Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.
- e) **For further guidance on funding, see the LIMITATION OF COSTS clause referenced in Part II, Contract Clauses.**

#### **G.6. GOVERNMENT PROPERTY**

- a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated into this contract by reference. This document can be accessed at:  
[http://oamp.od.nih.gov/sites/default/files/appendix\\_q\\_hhs\\_contracting\\_guide.pdf](http://oamp.od.nih.gov/sites/default/files/appendix_q_hhs_contracting_guide.pdf)

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Requests for information regarding property under this contract should be directed to the Contracting Officer.

- b. Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated in this contract in paragraph a. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

#### **G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

- a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation will be prepared after completion of one year of performance.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

- b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address: <http://www.cpars.gov>.

#### **G.8. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)**

- a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
- b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

- c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

#### **G.9. INDIRECT COST RATES**

In accordance with FAR 42.704, the following provisional billing rates are hereby established for Cue Health Inc., for invoicing under the this contract until final rates have been negotiated for FY 2018. Changes to provisional rates shall be negotiated from time to time thereafter as appropriate, subject to the ceiling rates below.

<b><u>Rate Type</u></b>	<b><u>Provisional Billing Rate</u></b>	<b><u>Contract Ceiling Rate</u></b>	<b><u>Allocation Base Description</u></b>
Fringe Benefits	20.61%	22.67%	Total Salaries and Wages
Overhead	63.71%	70.08%	Direct Salaries and Wages plus Applicable Fringe Benefits
G&A	18.87%	20.76%	Modified Total Direct Cost Input *

\*MTDC base excludes equipment, subcontracts and G&A expenses

The above also contains ceiling rates for the contract. Under the provisions of the ceiling rates, (1) the Government will not be obligated to pay any additional amounts should the final indirect cost rates exceed the ceiling rates, and (2) in the event the final indirect cost rates are less than the negotiated ceiling rates, the negotiated rates will be reduced to conform to the lower rates.

The above provisional rates are not final, nor do they relieve Cue of its responsibility to submit certified final indirect cost rate proposals required by FAR 52.216-7(d).

## **G10. OVERTIME COMPENSATION**

No overtime (premium) compensation is authorized under the subject contract. Billing of labor costs shall be limited to total actual hours worked in the billing period.

## **SECTION H - SPECIAL CONTRACT REQUIREMENTS**

### **H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)**

- a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current federal wide Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.
- b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.
- c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: <http://www.hhs.gov/ohrp/policy/guidanceonalternativeofwa.pdf>).
- d. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

### **H.2. HUMAN SUBJECTS**

Research projects involving humans and/or human specimens can only be initiated with written approval by the Contracting Officer's Representative.

The Good Clinical Practice Regulations (GCP)(21 CFR Parts 50, 54, 56)(45 CFR Part 46)(ICH E6) as well as other

applicable Federal and state regulations will be standards that apply for use of human subject and/or human specimens in clinical studies.

If at any time during the life of the contract, the Contractor fails to comply with GCP as identified by regulations outline above, the Contractor shall have thirty (30) Calendar days from the time such material failure is identified to cure such or initiate cure to the satisfaction of the Government Contracting Officer's Representative. If the Contractor fails to take such an action within the thirty (30) Calendar day period, then the contract may be terminated.

### **H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)**

- a. The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

### **H.4 MANUFACTURING STANDARDS**

The Good Manufacturing Practice Regulations (GMP)( pertaining to diagnostic products (21 CFR Part 820, Quality System Regulation) apply to manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Contractor fails to take such an action to the satisfaction of the Contracting Officer's Representative within the thirty (30) calendar day period, then the contract may be terminated.

### **H.5. NEEDLE DISTRIBUTION**

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or

syringes for the hypodermic injection of any illegal drug.

## **H.6 RESERVED**

## **H.7. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

## **H.8. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION**

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

## **H.9. PRIVACY ACT APPLICABILITY**

- 1) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at

<http://www.gpo.gov/fdsys/granule/CFR-2007-title45-vol1/CFR-2007-title45-vol1-part5b>

- 2) The COR is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

- 3) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link:

<http://www.hhs.gov/foia/privacy/sorns.html>

## **H.11 RESERVED**

## **H.12. CONFLICT OF INTEREST**

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to

commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the Contractor may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

#### **H.13 RESERVED**

#### **H.14. PUBLICATION AND PUBLICITY**

Except for necessary release to approved subcontractors and in connection with regulatory reporting requirements, no information related to data obtained under this contract shall be released or publicized without the prior written consent of BARDA. In this case, BARDA will be informed no later than the regulatory agency requiring the information.

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. .

For purposes of this contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for BARDA review no less than thirty (30) Calendar days for manuscripts and fifteen (15) Calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201XXX

#### **H.15. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in HHS funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The website to file a complaint on-line is:

<http://oig.hhs.gov/fraud/hotline/> and the mailing address is:

US Department of Health and Human Services  
Office of Inspector General  
ATTN: OIG HOTLINE OPERATIONS  
P.O. Box 23489  
Washington, D.C. 20026

#### **H.16. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES**

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

#### **H.17. USE OF FUNDS FOR PROMOTIONAL ITEMS**

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

#### **H.18. EPA ENERGY STAR REQUIREMENTS**

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

#### **H.19 RESERVED**

#### **H.20. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)**

- a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

- b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.
- c. The Contractor agrees that the care, use and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.
- d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Assurances.

**Note:** The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: [ace@aphis.usda.gov](mailto:ace@aphis.usda.gov) ; Web site: [http://www.aphis.usda.gov/animal\\_welfare](http://www.aphis.usda.gov/animal_welfare) .

## **H.21. ANIMAL WELFARE**

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: <http://grants1.nih.gov/grants/olaw/references/phspol.htm>

## **H.22. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS**

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

## **H.23. GUN CONTROL**

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

## **H.24 RESERVED**

## **H.25. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individuals are considered to be essential to the work being performed hereunder:

Individual	Organization	Role
Ayub Khattak	Cue Health, Inc	CEO, PI
Andy Hudak	Cue Health, Inc	Program Manager Lead
Deborah Morris	Cue Health, Inc	Director, Regulatory and Clinical Affairs
Siaw-Yen Lim	Cue Health, Inc	Director, Quality
Chi-Hui Liang	Cue Health, Inc	Director of Research and Development

#### **H.26. HIGHLY PATHOGENIC AGENTS**

The work being conducted under this contract may involve a Highly Pathogenic Agent (HPA). The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) and can be accessed at <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>
2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body,
3. The Contractor's appropriate designated institutional biosafety official, or
4. Documentation of compliance with CDC and USDA Select Agent Programs, where appropriate, for example in the case of testing with highly pathogenic avian influenza viruses (e.g. H5N1 and H7N9).

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

#### **H.27. CLINICAL RESEARCH**

These Clinical Terms apply to all grants and contracts that involve clinical research.

The Government shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports first produced and funded by the Government under this contract, as defined in

Rights in Data Clause in FAR 52.227-14 (Alternative II). The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form, to ensure the Government has the ability to review and distribute the deliverables, as the Government deems necessary within the context of this contract.

## **H.28. SAFETY AND MONITORING ISSUES**

Institutional Review Board (IRB) or Independent Ethics Committee (IEC) Approval

Before award and then with the annual progress report, the Contractor must submit to the Government a copy of the current IRB or IEC approved informed consent document, documentation of continuing review and approval and the Office of Human Research Protections (OHRP) FWA number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide the Government initial and annual documentation of continuing review and approval, including the current approved informed consent document and FWA number.

The grantee institution must ensure that the applications as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the Government a summary explanation and copies of documents related to all major changes in the status of ongoing protocols, including the following:

1. All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
2. All changes in informed consent documents, identified by version number, date, or both and dates it is valid.
3. Termination or temporary suspension of patient accrual.
4. Termination or temporary suspension of the protocol.
5. Any change in IRB approval.
6. Any other problems or issues that could affect the participants in the studies.

Contractors must notify BARDA through the Contracting Officer's Representative (COR) or Contracting Officer (CO) of any of the above changes by email within 72 hours for items 3 – 6 and 7 days for items 1 – 2, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an Institutional Bio-safety Committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

## **H.29 RESERVED**

## **H.30. BARDA PROTOCOL REVIEW PROCESS BEFORE PATIENT ENROLLMENT BEGINS**

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must provide the following (as applicable) for review by the Government:

1. Draft clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
2. Documentation of IRB or IEC approval, including OHRP FWA number, IRB or IEC registration number, and IRB or IEC name.
3. Draft informed consent template, identified by version number, date, or both and date it is valid.
4. Plans for the management of side effects.
5. Procedures for assessing and reporting adverse events.
6. Plans for data and safety monitoring, and monitoring of the clinical study site, pharmacy, and laboratory.
7. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received Good Clinical Practice (GCP) training in the protection of human subjects.

BARDA comments will be forwarded to the Contractor within two weeks (10 business days) of receipt of the above information. The Contractor must address in writing all study design, safety, regulatory, ethical, and conflict of interest concerns raised by the COR to the satisfaction of the Government before patient accrual or participant enrollment can begin. After the Government receives the corrected documentation, a written Contracting Officer Authorization (COA) Letter will be provided to the Contractor. This COA provides authorization to the Contractor to execute the specific clinical study funded in part or in whole by the Government.

### **H.31. REQUIRED TIME SENSITIVE NOTIFICATION**

Under the contract, the Contractor must submit to the Contracting Officer's Representative (COR) as follows:

1. *Expedited safety report of unexpected or life-threatening experience or death* – A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted within 24 hours of knowledge or when Contractor should have known of the event.
2. *Expedited safety reports of serious, and unexpected adverse experiences* – A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the Contracting Officer's Representative within 48 hours of the occurrence of the event.
3. *IDE reports of unanticipated adverse device effect* – A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the BARDA Contracting Officer's Representative within 24 hours of the occurrence of the event.
4. *Expedited safety reports* – should be sent to the COR concurrently with the report to FDA.
5. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to the BARDA annually.

In case of problems or issues, the COR will contact the Contractor within 10 working days by email, followed within 7 calendar days by an official letter to the Contractor. The Contractor shall forward the official letter to the principal investigator listing issues and appropriate actions to be discussed.

*Safety reporting for research not performed under an IND or IDE*

Ongoing safety reporting requirements for research not performed under an IND or IDE shall be mutually agreed upon by the Contracting Officer's Representative and the Contractor.

### **H.32. BARDA CLINICAL TRIAL DATABASE INFORMATION REPORTING**

The contractor must be prepared to provide initial information on each clinical study conducted under this contract to the COR. Study specific information is required at study start-up and regular updates on site by site enrollment will be required. Study specific information may include phase of study, ages of subjects being studied, number of subjects planned, estimated start and completion dates, subcontractor information and role on study, clinical site information. Clinical site information may include site Principal Investigator, location, FWA number and expiration date, certification of site human subjects training as required by OHRP.

Updated information on enrollment will include site by site enrollment including the number of subjects screened, enrolled (dosed), withdrew, and completed. Enrollment information will be provided on a regular basis as determined by the CO prior to study start.

It is expected to have an electronic transfer of study-specific data sets from the Contractor's automated information management systems or other data sources and files directly to a secure data capture system known as the BARDA Tracking Tool. Standard Data Submissions refers to the electronic transfer of study-specific, de-identified data sets from the contractor's automated information management systems or other data sources directly to another automated information management system. BARDA's information management system is automated. Submission of data to BARDA's system will be done through secure file transfer protocol (sFTP). Data submission can be done manually or automatically, depending on the contractor's preference and capability. Similarly, in most cases data will be able to be automatically generated from a contractor's system. The BARDA Tracking Tool will go through a testing phase to ensure appropriate handover of data from contractors. BARDA's secure data capture system is known as the BARDA Tracking Tool or BTT.

## **PART II – CONTRACT CLAUSES**

### **SECTION I – CONTRACT CLAUSES**

FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

#### **I.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CLAUSES**

Full text of the FAR clauses may be accessed electronically at: <https://www.acquisition.gov/far/index.html>

<u>FAR</u> <u>CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.202-1	Nov 2013	Definitions
52.203-3	Apr 1984	Gratuities
52.203-5	May 2014	Covenant Against Contingent Fees
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
52.203-7	May 2014	Anti-Kickback Procedures

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over \$150,000)
52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
52.203-14	Oct 2015	Display of Hotline Poster(s)
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
52.204-7	Oct 2016	System for Award Management
52.204-10	Oct 2016	Reporting Executive Compensation and First-Tier Subcontract Awards
52.204-13	Jul 2013	System for Award Management Maintenance
52.209-6	Oct 2016	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
52.209-9	Jul 2013	Updates of Publicly Available Information Regarding Responsibility Matters
52.209-10	Nov 2015	Prohibition on Contracting With Inverted Domestic Corporations
52.210-1	Apr 2011	Market Research
52.215-2	Oct 2010	Audit and Records – Negotiation
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
52.215-17	Oct 1997	Waiver of Facilities Capital Cost of Money
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges
52.216-7	Jun 2013	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.219-8	Nov 2016	Utilization of Small Business Concerns
52.222-2	Jul 1990	Payment for Overtime Premiums (The use of overtime is authorized under this contract if the overtime premium does not exceed * <u>\$0</u> ; See <u>G.10</u> )
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Sep 2016	Equal Opportunity
52.222-35	Oct 2015	Equal Opportunity for Veterans
52.222-36	Jul 2014	Affirmative Action for Workers with Disabilities
52.222-37	Feb 2016	Employment Reports on Veterans
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification
52.223-6	May 2011	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
52.224-1	April 1984	Privacy Act Notification
52.224-2	April 1984	Privacy Act

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	May 2014	Rights in Data-General
52.227-14 –Alternate II	Dec 2007	<p>Rights in Data – General, Alternate II. Completed portion as follows: Limited Rights Notice (Dec 2007)</p> <p>(a) These data are submitted with limited rights under Government Contract No <u>HHSO1002018000XXC</u>. These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, provided that the Government makes such disclosure subject to prohibition against further use and disclosure:</p> <ul style="list-style-type: none"> <li>(i) Use (except for manufacture) by support service contractors.</li> <li>(ii) Evaluation by nongovernment evaluators.</li> </ul> <p>(b) This Notice shall be marked on any reproduction of these data, in whole or in part.</p>
52.227-16	Jun 1987	Additional Data Requirements
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jan 2017	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer—System for Award Management
52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2014	Penalties for Unallowable Costs (Over \$700,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Oct 2010	Subcontracts (June 2007)
52.244-5	Dec 1996	Competition in Subcontracting
52.244-6	Nov2017	Subcontracts for Commercial Items
52.245-1	Jan 2017	Government Property, Alternate II (Apr 2012)
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability
52.247-63	Jun 2003	Preference for U.S.-Flag Air Carriers
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.251-1	Apr 2012	Government Supply Sources

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.253-1	Jan 1991	Computer Generated Forms

**I.2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR Chapter 3) CLAUSES**

Full text of the HHSAR clauses can be found at <http://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/tocindetail/index.html>.

<u>HHSAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
352.203-70	Dec 2015	Anti-Lobbying
352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
352.223-70	Dec 2015	Safety and Health
352.224-70	Dec 2015	Privacy Act
352.227-70	Dec 2015	Publications and Publicity
352.231-70	Dec 2015	Salary Rate Limitation
352.233-71	Dec 2015	Litigation and Claims
352.237-75	Dec 2015	Key Personnel
352.270-4b	Dec 2015	Protection of Human Subjects
352.270-6	Dec 2015	Restriction on use of Human Subjects

**I.3. ADDITIONAL CONTRACT CLAUSES**

**I.3.1. Additional Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clauses – In Full Text**

This contract incorporates the following clauses in full text.

**FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:**

**a. FAR Clause 52.217-9, Option to Extend the Term of the Contract (Mar 2000)**

(1) The Government may extend the term of this contract by written notice to the Contractor within 30 days after the Government has completed its analysis of the deliverables associated with the applicable milestone. The Government will provide the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(2) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(3) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 5 years.

**b. FAR Clause 52.219-28, Post-Award Small Business Program Representation (Jul 2013).**

(a) *Definitions.* As used in this clause--

*Long-term contract* means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

*Small business concern* means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is “not dominant in its field of operation” when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts—

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at <http://www.sba.gov/content/table-small-business-size-standards>.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor’s current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it [X ] is, [ ] is not a small business concern under NAICS Code 541711 assigned to contract number HHSO100201800016C. [Contractor to sign and date and insert authorized signer’s name and title].



Date: 06/04/2018

b. 52.232-40 – Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)

(a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise

required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

(b) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

(c) Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

## **PART III – ATTACHMENTS**

### **SECTION J – LIST ATTACHMENTS**

The following documents are attached and incorporated in this contract:

**Attachment 1:** Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Reimbursement Type Contracts.

**Attachment 2:** Sample Invoice Form

**Attachment 3:** Financial Report of Individual Project/Contract

**Attachment 4:** Safety and Health, HHSAR Clause 352.223-70, dated 1/2006

**Attachment 5:** Disclosure of Lobbying Activities, SF-LLL, dated 7/1997.

Located at: <http://www.whitehouse.gov/sites/default/files/omb/grants/sflllin.pdf>.

**Attachment 6:** Report of Government Owned, Contractor Held Property, dated 10/2014.

Located at: <http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Govt-Owned-Prop.pdf>

**Attachment 7:** Statement of Work

**Attachment 8:** Subject Inventions

#### **ATTACHMENT #1**

##### **INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS**

**Format:** Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

**Number of Copies:** Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

**Frequency:** Payment requests shall not be submitted more frequently than once monthly in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

**Cost Incurrence Period:** Costs incurred must be within the contract performance period or covered by pre-contract cost provisions.

**Billing of Costs Incurred:** If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s)

in which it incurred such costs.

**Contractor's Fiscal Year:** Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

**Currency:** All BARDA contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

**Costs Requiring Prior Approval:** Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

**Invoice/Financing Request Identification:** Each payment request shall be identified as either:

- (a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.
- (b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.
- (c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

**Preparation and Itemization of the Invoice/Financing Request:** The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

- (a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.
- (b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).
- (c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.
- (d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.
- (e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).
- (f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.
- (g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.
- (h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.
- (i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.
- (j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.
- (k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.
- (l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.
- (m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.
- (n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.
- (o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.
  - (1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by

personnel, and amount claimed.

- (2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.
- (3) **Accountable Personal Property:** Include any property having a unit acquisition cost of \$5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Control of Government Property*)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

- Item number for the specific piece of equipment listed in the Property Schedule, and
- COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

- (4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.
- (5) **Premium Pay:** List remuneration in excess of the basic hourly rate.
- (6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.
- (7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.
- (8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).
- (9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over \$1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.
- (p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.
- (q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.
- (r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.
- (s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.
- (t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.
- (u) **Grand Totals**
- (v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:  
"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

**\*\*Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.**

**ATTACHMENT #2**  
**SAMPLE INVOICE FORM**

Company Name

<b>Designated Billing Office Name and Address:</b>  DHHS/OS/ASPR/AMCG Attn: Contracting Officer 200 C St., S.W.  Washington, D.C. 20201  <b>Contractor's Address and Contact Information:</b>          POC: Name of accountant or COO or signatory authority for invoice Title: Phone: E-Mail:  <b>TIN:</b> <b>DUNS #:</b>	<b>Invoice/Finance Number:</b>  <b>Date Invoice Prepared:</b>  <b>Contract No.</b>  <b>Effective Date:</b>  <b>Total Estimated Cost of Order:</b>  <b>Office of Acquisitions:</b> Contracting Officer (insert name here) Office of Acquisitions Management, Contracts, and Grants (AMCG)  <b>Central Point of Distribution:</b>
--	--

This invoice represents reimbursable costs for the period from

Expenditure Category	Amount Billed		Contract Value
	Current	Cumulative	
<b>Direct Costs:</b>			
Direct Labor			
Fringe Benefits 0.00%			
<b>Total Labor Costs:</b>			
<b>Overhead 0.00%</b>			
Travel			
Subcontracts			
Consultant Fees			
Materials and Supplies			
Other			
<b>Total Direct Costs</b>			
G&A Rate 0.00%			
Subtotal:			
Fixed Fee 0.0%			
Total Amount Claimed			
Adjustments			
<b>Grand Total</b>	\$ -		

I certify that all payments requested are for appropriate purposes and in accordance with the contract.

\_\_\_\_\_  
 Name/signature of signatory authority for invoicing

ATTACHMENT #3

**INSTRUCTIONS FOR COMPLETING  
"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT" GENERAL**

**INFORMATION**

**Purpose.** This Quarterly Financial Report is designed to: (1) provide a management tool for use by be BARDA in monitoring the application of financial and personnel resources to the BARDA contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

**REPORTING REQUIREMENTS**

**Scope.** The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

**Number of Copies and Mailing Address.** An original copy of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the Contracting Officer's Technical Representative.

**REPORTING STATISTICS**

A modification which extends the period of performance of an existing contract will not require reporting on a separate quarterly report, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

**Definitions and Instructions for Completing the Quarterly Report.** For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

- (1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.
- (2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

- (3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.
- (4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of \$1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."
- (5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.
- (6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.
- (7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.
- (8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.
- (9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.
- (10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.
- (11) **Subcontracts.** List each subcontract by name and amount billed.
- (12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.
- (13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.
- (14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.
- (15) **Fee.** Cite the fee earned, if any.
- (16) **Total Costs to the Government.**

## **PREPARATION INSTRUCTIONS**

These instructions are keyed to the Columns on the Quarterly Report.

**Column A--Expenditure Category.** Enter the expenditure categories required by the contract.

**Column B--Percentage of Effort/Hours Negotiated.** Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

**Column C--Percentage of Effort/Hours-Actual.** Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

**Column D--Cumulative Incurred Cost at End of Prior Period.** Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

**Column E--Incurred Cost-Current Period.** Enter the costs which were incurred during the current period.

**Column F--Cumulative Incurred Cost to Date.** Enter the combined total of Columns D and E.

**Column G--Estimated Cost to Complete.** Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

**Column H--Estimated Costs at Completion.** Complete only if an entry is made in Column G.

**Column I--Negotiated Contract Amount.** Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

**Column J--Variance (Over or Under).** Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

**Modifications.** List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

**Expenditures Not Negotiated.** List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

**HHSAR 352.223-70 SAFETY AND HEALTH (December 2015)**

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.

(1) In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:

(i) *29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR part 1910. These regulations are available at <https://www.osha.gov/>.*

(ii) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (**42 U.S.C. 5801 et seq.**). The Contractor may obtain copies from the **U.S. Nuclear Regulatory Commission**, Washington, DC 20555-0001.

(2) The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:

(i) Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at <http://www.cdc.gov/biosafety/publications/index.htm>.

(ii) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street, NW., Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication is available at <http://www.nap.edu/catalog/4911/prudent-practices-in-the-laboratory-handling-and-disposal-of-chemicals>.

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the Contracting Officer's Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable "Changes" clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report citing all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall form the basis for a request for extension or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions

(End of Clause)

## ATTACHMENT #5

## DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352

0348-0046

(See reverse for public burden disclosure.)

<b>1. Type of Federal Action:</b> <input type="checkbox"/> a. contract <input type="checkbox"/> b. grant <input type="checkbox"/> c. cooperative agreement d. loan <input type="checkbox"/> e. loan guarantee f. loan insurance	<b>2. Status of Federal Action:</b> <input type="checkbox"/> a. bid/offer/application <input type="checkbox"/> b. initial award <input type="checkbox"/> c. post-award	<b>3. Report Type:</b> <input type="checkbox"/> a. initial filing <input type="checkbox"/> b. material change <b>For Material Change Only:</b> year _____ quarter _____ date of last report _____
<b>4. Name and Address of Reporting Entity:</b> Prime _____ Subawardee _____ Tier _____, if known : _____  Congressional District, if known : _____		<b>5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:</b>   Congressional District, if known : _____
<b>6. Federal Department/Agency:</b>	<b>7. Federal Program Name/Description:</b>  CFDA Number, if applicable: _____	
<b>8. Federal Action Number, if known :</b>	<b>9. Award Amount, if known :</b> \$ _____	
<b>10. a. Name and Address of Lobbying Entity</b> (if individual, last name, first name, MI): _____	<b>b. Individuals Performing Services</b> (including address if different from No. 10a) (last name, first name, MI): _____	
(attach Continuation Sheet(s) SF-LLA, if necessary)		
<b>11. Amount of Payment</b> (check all that apply): \$ _____ <input type="checkbox"/> actual <input type="checkbox"/> planned	<b>13. Type of Payment</b> (check all that apply): <input type="checkbox"/> a. retainer <input type="checkbox"/> b. one-time fee c. <input type="checkbox"/> commission <input type="checkbox"/> d. contingent fee e. <input type="checkbox"/> deferred f. other; specify: _____	
<b>12. Form of Payment</b> (check all that apply): <input type="checkbox"/> a. cash b. in-kind; specify: nature _____ value _____		
<b>14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11:</b>   (attach Continuation Sheet(s) SF-LLA, if necessary)		
<b>15. Continuation Sheet(s) SF-LLA attached:</b> Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>16.</b> Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.	Signature: _____ Print Name: _____ Title: _____ Telephone: _____ No.: _____ Date: _____	
<b>Federal Use Only:</b>		Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

## INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLLA Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, State and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.  
  
(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLLA Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is OMB No. 0348-0046. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, DC 20503.

**ATTACHMENT #6**

<b>REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY</b>							
CONTRACTOR:				CONTRACT NUMBER			
ADDRESS				REPORT DATE:			
				FISCAL YEAR:			
CLASSIFICATION	BEGINNING OF PERIOD		ADJUSTMENTS			END OF PERIOD	
	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND>=\$25K							
LAND<\$25K							
OTHER REAL>=\$25K							
OTHER REAL<\$25K							
PROPERTY UNDER CONST>=\$25K							
PROPERTY UNDER CONST<\$25K							
PLANT EQUIP>=\$25K							
PLANT EQUIP<\$25K							
SPECIAL TOOLING >= \$25K							
SPECIAL TOOLING<\$25K							
SPECIAL TEST EQUIP>=\$25K							
SPECIAL TEST EQUIP<\$25K							
AGENCY PECULIAR>=\$25K							
AGENCY PECULIAR<\$25K							
MATERIAL>=\$25K (CUMULATIVE)							
PROPERTY UNDER MFR>=\$25K							
PROPERTY UNDER MFR<\$25K							
SIGNED BY:							
(SIGNATURE) _____ (NAME							
PRINTED) _____ (TITLE) _____							
				DATE SIGNED:			
				_____  (TELEPHONE) _____			

## ATTACHMENT #7

### F. Statement of Work

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

#### **BASE CONTRACT - Cue Health Monitoring System with Cue Influenza Cartridge and Cue Health Mobile App and Cue Professional Mobile App**

##### **Objective**

To accelerate the development, validation, regulatory authorization, and commercialization of the over-the-counter (OTC) and professional point-of-care (POC)/CLIA Waived Cue Influenza Cartridge for use with the Cue Health Monitoring System and the Cue Health Mobile Application for lay users and the Cue Professional Mobile Application for professional operators. Activities described herein will result in:

- Separate 510k submissions for the Cue Health Monitoring System with Cue Influenza Cartridge for OTC and POC/CLIA Waived claims in May 2019
- Expected 510k clearances and commercial availability of both the OTC and professional products in October 2019

##### **PROGRAM MANAGEMENT (WBS 1.1.1):**

The Contractor shall provide for the following as outlined below:

- The overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;
- A principal investigator (PI) responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors; the contract deliverables list identifies all deliverables and reporting requirements for this contract.
- Project manager(s) responsible for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities; costs incurred; and program activities.
- A BARDA liaison responsible for effective communication with the project officer and contracting officer.
- Administrative/legal staff to provide development of compliant subcontracts, consulting, and other legal agreements, and ensure timely acquisition of all proprietary rights, including IP rights, and reporting all inventions made in the performance of the project.
- Administrative staff with responsibility for financial management and reporting on all activities conducted by the contractor and any subcontractors.

## **ASSAY DEVELOPMENT (WBS 1.1.2):**

Assay development activities conducted under this proposal will include primer optimization for triplex, formulation optimization, mixing optimization, and valve optimization. Cue R&D will conduct in-house analytical validation studies for the Cue Health Monitoring System and Cue Influenza Cartridge in support of 510k OTC and POC/CLIA Waived clearance.

**WBS/IMS Task 1.1.2.1: Primer optimization for triplex, formulation optimization, mixing optimization, and valve optimization.** Specific tasks include: primer screening and buffer optimization (WBS 1.1.2.1.1) and triplex detection development in cartridge, amplification protocol with piezo in cartridge, and triplex electrochemical detection in cartridge (WBS 1.1.2.1.1 - 1.1.2.1.3). Deliverable is

the report on optimization of triplex primer set, formulation optimization of buffer and lyophilization recipe, mixing optimization, and valving optimization.

**WBS/IMS Task 1.1.2.2: Limit of Detection Study.** Specific activities include prepare study protocol; prepare sample panel; execute study; preparation and approval of study report (WBS 1.1.2.2.1 - 1.1.2.2.4). Deliverable is study report.

**WBS/IMS Task 1.1.2.3: Qualify mucin matrix for sample panels and Demonstrate assay compatibility with different nasal fluid properties.** Evaluate various types of mucin for performance in Cue Influenza Cartridge. Deliverable is approved study report. Specific activities include prepare study protocol; prepare sample panel; execute study; preparation and approval of study report (WBS 1.1.2.3.1 - 1.1.2.3.4). Deliverable is study report.

**WBS/IMS Task 1.1.2.4: Intra- and inter-assay precision and lot-to-lot agreement.** Specific activities include prepare study protocol; prepare sample panel; execute study; preparation and approval of study report (WBS 1.1.2.4.1 - 1.1.2.4.4). Deliverable is study report.

**WBS/IMS Task 1.1.2.5: Analytical Reactivity (inclusivity) Studies.** Specific activities include prepare study protocol; prepare sample panel; execute study; preparation and approval of study report (WBS 1.1.2.5.1 - 1.1.2.5.4). Deliverable is study report.

**WBS/IMS Task 1.1.2.6: Analytical Specificity (exclusivity and cross-reactivity) Studies.** Specific activities include prepare study protocol; prepare sample panel; execute study; preparation and approval of study report (WBS 1.1.2.6.1 - 1.1.2.6.4). Deliverable is study report.

**WBS/IMS Task 1.1.2.7: Analytical Specificity (potential interferents) Studies.** Specific activities include prepare study protocol; prepare sample panel; execute study; preparation and approval of study report (WBS 1.1.2.7.1 - 1.1.2.7.4). Deliverable is study report.

**WBS/IMS Task 1.1.2.8: Specimen Stability Study.** Specific activities include prepare study protocol; prepare sample panel; execute study; preparation and approval of study report (WBS 1.1.2.8.1 - 1.1.2.8.4). Deliverable is study report.

**WBS/IMS Task 1.1.2.9: Flex/Guard-band studies.** Specific activities include prepare study protocol; prepare sample panel; execute study; preparation and approval of study report (WBS 1.1.2.9.1 - 1.1.2.9.4). Deliverable is study report.

**WBS/IMS Task 1.1.2.10: Cartridge Stability Studies.** Specific activities include prepare study protocol; prepare sample panel; execute study; preparation and approval of study report (WBS 1.1.2.10.1 - 1.1.2.10.4). Deliverable is study report.

**WBS/IMS Task 1.1.2.11: Cartridge Shipping Stability and Shipping Stress Studies.** Specific activities include Prepare study protocol; prepare sample panel; execute study; preparation and approval of study report (WBS 1.1.2.11.1 - 1.1.2.11.4). Deliverable is study report.

**WBS/IMS Task 1.1.2.12:** Milestone- Analytical Performance Studies completed.

### **CLINICAL (WBS 1.1.3):**

In support of 510k clearance for the OTC claim, Cue will conduct clinical studies to generate data for:

- Human Factors/Usability with lay users simulating self-testing and a Pilot Study with lay users self-collecting their nasal sample using the Cue sample wand and self-testing their nasal sample
- Repeatability/Reproducibility at external clinical sites
- Detection of Samples at the Limit of Detection at clinical sites
- Method Comparison of OTC Cue Influenza to a predicate FDA-cleared Influenza A/B NAT assay with enrolled subjects (lay users self-testing and enrolled parents testing their enrolled children) at clinical sites in a simulated at-home environment

In support of 510k clearance for the professional POC/CLIA Waived claim, Cue will conduct clinical studies to generate data for:

- Human Factors/Usability with professional operators simulating testing patients
- Repeatability/Reproducibility at external clinical sites (same study as for OTC claim)
- Detection of Samples at the Limit of Detection at clinical sites (same study as for OTC claim)
- Method Comparison of POC/CLIA Waived Cue Influenza to a predicate Influenza A/B NAT assay with professional trained and untrained operators testing enrolled subjects (includes parent testing his/her child)

Further description of the studies that will be conducted as part of the clinical validation of Cue Influenza at external clinical sites is presented below.

**WBS/IMS Task 1.1.3.5: Human Factors/Usability Studies and Pilot Study with Lay Users Self- Testing.** The purpose of the Cue Human Factors/Usability Validation Studies (Usability Studies) is to assess user interactions with the device user interface to identify any use errors that would or could result in serious harm to the patient or user. Usability Studies will be conducted with lay users and professional operators at a minimum of 3 US sites. Study sites will include simulated home and simulated CLIA Waived professional environments. The sample size will be approximately 100 lay users and 100 professional operators. After completion of a task list, the study participant will complete a usability questionnaire relevant to performing the Cue Influenza test using the Cue Health Monitoring System, Cue Influenza Cartridge and the lay user Cue Health Mobile Application or the Cue Professional Mobile Application. The purpose of the Cue Pilot Study with Lay Users Self-Testing (Pilot Study with Lay Users) is to demonstrate that the Cue Influenza test can detect influenza viruses in lay user self-collected and self-tested nasal samples. In addition, the comparison of Cue Influenza results to institutional flu test results will be evaluated (preliminary sensitivity and specificity data). The Pilot Study with Lay Users will be conducted at 2 sites in the southern hemisphere (eg, 2 sites in Australia) due to timing of the flu season and the need to conduct this study prior to the clinical validation studies. The sample size will be approximately 100 lay users that are at least 18 years of age with signs/symptoms of influenza-like illness. After undergoing informed consent and being confirmed as eligible for the study (meets inclusion criteria and does not meet the exclusion criteria), the subject will self-collect his/her nasal sample using the Cue sample wand and test the sample in Cue Influenza Cartridge. After testing, the subject will complete a brief usability questionnaire.

Specific activities include: Preparation of Usability Study Protocol and Pilot Study Protocol, Questionnaires, SAP, DM Plan and eDatabase (WBS 1.1.3.5.1 – 1.1.3.5.6); Site qualification and selection for both the

Usability and Pilot Study with Lay Users (WBS 1.1.3.5.7); Site contracts and IRB approvals for both the Usability and Pilot Study with Lay Users (WBS 1.1.3.5.8 – 1.1.3.5.10); Site preparation and initiation for both the Usability and Pilot Study with Lay Users (WBS 1.1.3.5.11 – 1.1.3.5.12); Execution of Usability Study and Pilot Study with Lay Users (WBS 1.1.3.5.13); Data management, analysis, reporting, and close-out for both studies (WBS 1.1.3.5.14 – 1.1.3.5.16). Deliverable is Usability Study report and Pilot Study with Lay Users report.

**WBS/IMS Task 1.1.3.6: Clinical Study Protocols, Statistical Analysis Plans, Data Management Plans and eDatabase.** Specific activities include preparation of OTC and POC/CLIA Waived Method Comparison, Reproducibility/Repeatability Study, and Samples at LoD Study Protocols (WBS 1.1.3.6.1); preparation of Statistical Analysis Plans (WBS 1.1.3.6.2); preparation of Data Management Plans (DMPs) and eDatabases (WBS 1.1.3.6.3 – 1.1.3.6.4). Deliverables are internal approval of OTC and POC/CLIA Waived Method Comparison, Reproducibility/Repeatability Study, and Samples at LoD Study Protocols, SAPs, and DMPs, and live eDatabases. **WBS/IMS Task 1.1.3.7 – 1.1.3.8: Clinical Study Site and Central Lab Qualification and Selection for Method Comparison, Reproducibility/Repeatability, and Samples at LoD Studies.** Specific activities include: development of site feasibility questionnaire, identification of potential sites, execution of non-disclosure agreement with potential investigators, conduct site qualification visits and reporting (WBS 1.1.3.7.1 – 1.1.3.7.8 and WBS 1.1.3.8.1 – 1.1.3.8.8). Deliverables are at least 16 clinical sites (8 sites for OTC and 8 sites for POC/CLIA Waived) and 1 central lab selected.

**WBS/IMS Task 1.1.3.9: Clinical Study Site Contracts.** Specific activities include: draft budgets and budget negotiation (WBS 1.1.3.9.1); draft contract and contract negotiations (WBS 1.1.3.9.2). Deliverables are clinical study contracts executed with clinical sites and central lab.

**WBS/IMS Task 1.1.3.10: Institutional Review Board (IRB) Submissions and Approvals of Each Clinical Validation Protocol.** Specific activities include: selection of IRB, completion of IRB protocol submission forms, draft informed consent forms, and submission and approval of method comparison study protocols and informed consent forms (WBS 1.1.3.10.1 – 1.1.3.10.4). Deliverables are IRB approval of OTC and POC/CLIA Waived Method Comparison, Reproducibility/Repeatability Study, and Samples at LoD Protocols.

**WBS/IMS Task 1.1.3.11: Clinical Study Materials.** Specific tasks include: ship Cue IUO devices, mobile smart devices, predicate devices and sample collection kits procurement and accountability at clinical sites (WBS 1.1.3.11.1 – 1.1.3.11.7). Deliverables are all clinical study materials at the clinical sites.

**WBS/IMS Task 1.1.3.12: Clinical Site Initiation.** Specific tasks include: preparation of Clinical Monitoring Plans, set up of Trial Master Files and Investigator Site Binders, creation of study-specific forms, conduct initiation visits and preparation and approval of initiation visit reports (WBS 1.1.3.12.1; 1.1.3.12.2.1 – 1.1.3.12.2.12). Deliverables are clinical sites initiated.

**WBS/IMS Task 1.1.3.13.1 – 1.1.3.13.4: Clinical Sites Reproducibility/Repeatability Study Conducted and Reported.** This study will demonstrate the reproducibility and repeatability of the Cue Influenza Cartridge assay. This study will be conducted at 3 external CLIA Waived clinical sites with 6 trained professional operators using identical panel members. The sample panel will contain 10 panel members. Two strains of influenza A virus and 1 strain of influenza B virus will be used to build the panel members. The influenza A virus panel members will contain high negative (<LoD; C<sub>20-80</sub>), low positive (LoD; C<sub>95</sub>), and moderate positive (2-3x LoD; C<sub>100</sub>) concentrations. The influenza B virus panel members will contain high negative (<LoD; C<sub>20-80</sub>), low positive (LoD; C<sub>95</sub>), and moderate positive (2-3x LoD; C<sub>100</sub>) concentrations. One panel member will be negative for influenza A and B viruses. At each site, 2 operators per day will conduct

testing and each operator will perform one run per day. Each operator will test 3 replicates of each sample panel per run.

Each site will conduct testing for 5 days. Each site will generate 30 results per sample for a total of 90 results per sample overall. Statistical analysis will include calculating percent agreement (compared to expected results based on panel member concentration) by panel member, by site and overall. Subtasks include: study execution (WBS 1.1.3.13.1.1 - 1.1.3.13.1.4); database lock, data review and analysis (1.1.3.13.2.1 – 1.1.3.13.2.8); study close-out (WBS 1.1.3.13.3.1 – 1.1.3.13.3.2); preparation of study report (WBS 1.1.3.13.4.1 – 1.1.3.13.4.5). Deliverable is reproducibility/repeatability study report.

**WBS/IMS Task 1.1.3.13.5 – 1.1.3.13.7: Clinical Sites Testing of Samples with Influenza Concentrations near the LoD Conducted and Reported.** This study will demonstrate the performance of Cue Influenza Cartridge with untrained professional users testing samples with influenza virus concentrations near the limit of detection. The study will be conducted at 3 external CLIA Waived clinical sites. Cue will prepare a contrived weak positive (C<sub>95</sub>) sample pool and a contrived weak negative (C<sub>5</sub>) sample pool for 2 influenza A strains and 2 influenza B strains (one from each lineage) detected by Cue Influenza and distribute aliquots of the pools to the sites for testing. At least 2 untrained operators at each site will conduct testing. For weak positive samples, the percent of Cue Influenza positive results will be calculated overall and by site. For weak negative samples, the percent of Cue Influenza negative results will be calculated overall and by site. Specific activities include: study execution (WBS 1.1.3.13.5.1 – 1.1.3.13.5.4); database lock, data review and analysis (WBS 1.1.3.13.6.1 – 1.1.3.13.6.8); study close-out (WBS 1.1.3.13.7.1 – 1.1.3.13.7.2); preparation of study report (WBS 1.1.3.13.8.1 – 1.1.3.13.8.5). Deliverable is Samples at LoD study report.

**WBS/IMS Task 1.1.3.14: OTC and POC/CLIA Waived Method Comparison Studies.**

The OTC and POC/CLIA Waived Method Comparison Studies will establish the clinical performance of the Cue Health Monitoring System with Cue Influenza Cartridge and Cue Health.

Mobile Applications in comparison to a predicate influenza A/B NAT assay. The prospective, non-interventional method comparison studies will be conducted in parallel at a minimum of 10 US and international clinical sites. Participating sites will enroll subjects for both the OTC and POC/CLIA Waived studies; however, no subject may participate in both studies. The study population will include subjects of all ages with signs and symptoms of influenza virus infection. The OTC study will enroll lay users who will self-collect and self-test their own nasal swab sample using Cue Influenza and the Cue Health Mobile Application to generate data in support of the OTC claim. The OTC study will also enroll parents collecting and testing his/her enrolled child's nasal sample. In the POC/CLIA Waived study, professional trained operators and professional untrained operators will test enrolled subjects (both adults and children) with Cue Influenza and the Cue Professional Mobile App to generate data in support of the POC/CLIA Waived claim. All predicate assay testing will be conducted by a professional trained operator in a CLIA Waived environment. The overall sample size is dependent on influenza prevalence during the clinical study, which varies by season, year and influenza type. The overall sample size across both the OTC and POC/CLIA Waived studies is approximately 4000 subjects, assuming a prevalence of approximately 5.5% for influenza B virus, to obtain a minimum of 220 samples positive results for influenza A, 220 samples with positive results for influenza B, and 220 samples with negative results. Cue Influenza results will be compared to the predicate method (e.g., FDA-cleared influenza A/B NAT assay) and positive and negative percent agreement will be calculated. Specific activities include: study execution (WBS 1.1.3.14.1.1 – 1.1.3.14.1.6); database lock, data review and analysis (WBS 1.1.3.14.2.1 – 1.1.3.14.2.10); study close-out (WBS 1.1.3.14.3.1 – 1.1.3.14.3.2);

preparation of study report (WBS 1.1.3.14.4.1 – 1.1.3.14.4.5). Deliverable is method comparison study report.

**WBS/IMS Task 1.1.3.15: BIMO Inspections.** Specific activities include clinical site and Cue preparation and mock inspections (WBS 1.1.3.15.1 – 1.1.3.15.2). Deliverable is mock BIMO inspections completed.

#### **REGULATORY (WBS 1.1.4):**

**WBS/IMS Tasks 1.1.4.1 – 1.1.4.3: Regulatory Submissions.** Preparing and submitting FDA 510k for Cue Influenza OTC claim and FDA 510(k) for Cue Influenza POC/CLIA Waived claim. Deliverables are FDA 510k OTC and POC/CLIA Waived submissions and clearances.

#### **BIOPRODUCTION MANUFACTURING (WBS 1.1.5):**

Bioproduction Manufacturing activities include enzyme and lyophilization process scale up, design freeze, validation and process transfer to GMP. These activities will take place after assay verification and result in a fully validated lyophilization process for production of cartridge lots for analytical and clinical validation studies.

**WBS/IMS 1.1.5.1: Enzyme Process Transfer and Validation.** Enzyme processes and specifications will be finalized and documentation completed. Upon completion of document approvals, the process validation of the enzyme processes will begin. After 3 successful preproduction lots of enzymes are made, the validation study of each enzyme process will be completed and reviewed. Lyophilization process development and verification will be conducted. Specific activities include preparation of enzyme process validation protocol, manufacture of enzymes and completion of validation report (WBS 1.1.5.1.1 – 1.1.5.1.4). Deliverable is enzyme process validation report.

**WBS/IMS 1.1.5.2: Lyophilization Process Development and Verification.** Lyophilization scale up process development, manufacture of 3 lots of reagent pellets and accelerated stability studies will also be performed on each enzyme lot generated (WBS 1.1.5.2.1 – 1.1.5.2.6). Deliverable is 3 preproduction lots of enzyme passing QC Specifications.

**WBS/IMS 1.1.5.3: Lyophilization Formulation Lock and Design Freeze.** Production lots of lyophilization pellets will be made, the lyophilization formulation will be locked and design freeze will be completed. Specific activities include preparation of internal certificate of analysis for production lots of and preparation of process transfer protocol and transfer to GMP will be initiated

(WBS 1.1.5.3.1 – 1.1.5.3.5). Deliverable is process transfer protocol.

**WBS/IMS 1.1.5.4: Lyophilization Process Transfer and Validation.** After 3 successful preproduction lots of lyophilization pellets are made, the lyophilization process validation will be completed. After the completion of lyophilization validation, the lyophilization process will be integrated into the Cue Influenza automation line to support manufacturing of Cue Influenza Cartridges for analytical and clinical validation. Specific activities include preparation of internal certificate of analysis for production lots, preparation of process transfer protocol, and transfer to GMP. The validation protocols for the lyophilization process will be prepared and IQ, OQ, and PQ validation efforts will be completed. Critical process parameters will be identified through FMEA risk assessments (WBS 1.1.5.4.1 – 1.1.5.4.8). Deliverable is lyophilization validation report.

**WBS/IMS 1.1.5.5 Bioproduction scale up for post 510k commercialization.**

#### **CARTRIDGE MANUFACTURING (WBS 1.1.6):**

Cartridge Automation Manufacturing activities include automation system design, approval, fabrication of manufacturing systems, validation of cartridge automation line and manufacture of Cue Influenza Cartridges for analytical and clinical validation. The systems that encompass the automation line for cartridge manufacturing are: 1500- PCB Processing Machine, 1501- Fluidic Subassembly Machine, 1502- Flavoring Machine, 1503- Finishing Machine, 1504- Cartridge Printing Machine, 1505- Cartridge Pouching Machine, 1506- Lyophilized Bead Dispense System, 1507- Fluid Wand Assembly Machine, 1701- Fluidic/PCB Assembly Machine, 1708- Fluidic Pre- Processing Machine and 1709- Wax-Dispense System.

**WBS/IMS 1.1.6.1: Development, fabrication, bring-up of systems 1500, 1501, 1502, 1503, 1504, 1505, 1506, 1507.** Work completed to date on the automation line. Deliverable is functional cartridge assembly equipment.

**WBS/IMS 1.1.6.2: Create system level drawings for each automation system/machine.**

Deliverable is completed system-level drawing for each automation machine.

**WBS/IMS 1.1.6.3: Write specification for each automation machine.** Deliverable is system- level specifications for each automation machine.

**WBS/IMS 1.1.6.4: Project approval for each system.** Deliverable is documented project approval for each system.

**WBS/IMS 1.1.6.5: Successful Design Review for Each System.** Deliverable is documented design review and approval completed for each system.

**WBS/IMS 1.1.6.6: Install Dry Room System for Manufacturing Cell.** Deliverable is documented validation for dry room performance.

**WBS/IMS 1.1.6.7: Fabrication of Each System (mechanical, electrical, pneumatics).**

Deliverable is fabrication of each system is completed.

**WBS/IMS 1.1.6.8: Initial Debug of Each System (able to produce a single part).**

Deliverable is each system debug is completed.

**WBS/IMS 1.1.6.9: Full System Runs-Optimize and Final Debug.** Deliverable is optimization and final debug completed.

**WBS/IMS 1.1.6.10: Documentation for Each System (e.g., Operation & Maintenance Manual, Spare Parts List).** Deliverable is documentation for each system is complete.

**WBS/IMS 1.1.6.11: Validation Protocols for Each System.** Deliverable is approved validation protocols for each system.

**WBS/IMS 1.1.6.12: Validate all Systems (IQ, OQ, PQ).** Deliverable is IQ, OQ, PQ complete and report approved for each system.

**WBS/IMS 1.1.6.13: Manufacture of Cue Influenza Cartridges for analytical and clinical validation.**

Manufacture of 3 lots of Cue Influenza Cartridges for analytical and clinical validation. **WBS/IMS 1.1.6.14: Manufacture scale up to meet cartridge sales post FDA 510(k) clearance**

**WBS/IMS 1.1.7: Quality:** Maintenance of ISO 13485 certification, quality audits, instrument

calibrations, QA and release batch records, oversee building and lab monitoring systems.

**WBS/IMS 1.1.8 Operations:** ERP, purchasing, supply chain and inventory management, production/quality team coordination

**WBS/IMS 1.1.9 Software:** Develop testing systems for iOS consumer and professional apps, software verification/validation/documentation, automated testing to ensure working order maintenance of

backend systems. Deliverable is validated Cue consumer and professional apps and ongoing software lifecycle documentation.

### **OPTION 1: Cue Health Monitoring System with Cue Multiplex Respiratory Pathogen Cartridge and Cue Health Mobile App**

#### **Objective**

The Cue Multiplex Respiratory Pathogen Cartridge will be a multiplex assay that will detect and differentiate influenza A and B viruses, as well as Influenza A subtypes (eg, H3N2 and H1N1) and detect respiratory syncytial virus (RSV) and human coronavirus (HCoV). To accelerate the development, validation, regulatory authorization, and commercialization of the OTC Cue Multiplex Respiratory Pathogen Cartridge for use with the Cue Health Monitoring System and the Cue Health Mobile App for lay users. Activities described herein will result in:

- 510k submission for the Cue Health Monitoring System with OTC Cue Multiplex Respiratory Pathogen Cartridge in September 2020
- Expected 510k clearance and commercial availability in February 2021

#### **PROJECT MANAGEMENT (WBS 1.2.1 Project Management)**

Overall management, integration and coordination of all contract activities; technical and administrative infrastructure (WBS 1.2.1.1).

**ASSAY DEVELOPMENT (WBS 1.2.2 Multiplex Respiratory Pathogen Assay Development)** Assay development activities conducted under this proposal will include assay feasibility, primer screening and buffer optimization, as well as development and optimization of the amplification protocol through the piezo and multiplex detection. In addition, analytical performance verification and validation studies will be conducted in-house to validate characteristics of the Cue Health Monitoring System with Cue Multiplex Respiratory Pathogen Cartridge.

**WBS/IMS Task 1.2.2.1 – 1.2.1.2: Off-cartridge Assay Feasibility, Cartridge Development.** Specific tasks include: primer screening and buffer optimization (WBS 1.2.2.1.1) and multiplex detection development in cartridge, amplification protocol with piezo in cartridge, and multiplex electrochemical detection in cartridge (WBS 1.2.2.2.1 - 1.2.2.2.3). Deliverable is the feasibility report.

**WBS/IMS Task 1.2.2.3: Design Verification Studies and Reporting.** Specific tasks include: preparation of study protocols, execution of studies and preparation of study reports for limit of detection, precision, specificity, potentially interfering substances, specimen matrices, and cartridge stability performance characteristics (WBS 1.2.2.3.1 - 1.2.2.3.5). Deliverable is study reports.

**WBS/IMS Task 1.2.2.4: Analytical Performance Validation and Reporting.** Specific tasks include: preparation of study protocols, execution of studies and preparation of study reports for limit of detection specimen matrices precision analytical specificity (exclusivity), analytical reactivity (inclusivity), lot-to-lot agreement, potentially interfering substances, specimen stability, cartridge stability, flex studies, cartridge shipping stability (WBS 1.2.2.4.1 - 1.2.2.4.10). Deliverable is study reports.

### **CLINICAL (WBS 1.2.3)**

In support of the 510k clearance for OTC Cue Multiplex Respiratory Pathogen Cartridge, Cue will conduct clinical studies at external sites to generate data for:

- Human Factors/Usability
- Repeatability/Reproducibility
- Detection of Samples at the Limit of Detection
- Method Comparison of Cue Multiplex Respiratory Pathogen Cartridge to a reference method(s) with lay users self-collecting and self-testing (includes parent testing his/her child)

Further description of the studies that will be conducted as part of the external site clinical validation of the Cue Multiplex Respiratory Pathogen Cartridge is presented in the following WBS/IMStasks.

**WBS/IMS 1.2.3.1-1.2.3.3: Clinical Plan and IUO Labeling.** Specific activities include: pre- submission to FDA and FDA feedback provided to Cue, Regulatory and Clinical Plans, collaboration on draft IUO Cue Multiplex Respiratory Pathogen Cartridge labeling. Deliverables are completed and approved regulatory and clinical plans and IUO labeling complete.

**WBS/IMS 1.2.3.4: Vendor Selection and Engagement.** Specific activities include: CRO qualification and selection, budget negotiation, contract executed and CRO training (WBS 1.2.3.6.1); eDC (electronic data capture system/eDatabase) vendor qualification and selection, budget negotiation, contract execution eDC (WBS 1.2.3.6.2). Deliverables are CRO/eDatabase vendor(s) contracted and engaged.

**WBS/IMS 1.2.3.5: Human Factors/Usability Studies.** The purpose of the Cue Human Factors/Usability Validation Studies (Usability Studies) is to assess user interactions with the device user interface to identify any use errors that would or could result in serious harm to the patient or user. Usability Studies will be conducted with lay users at a minimum of 3 US sites. Study sites will include simulated home environment. The sample size will be approximately 100 lay users. After completion of a task list, the study participant will complete a usability questionnaire relevant to performing the Cue Multiplex Respiratory Pathogen test using the Cue Health Monitoring System, Cue Multiplex Respiratory Pathogen Cartridge and the lay user Cue Health Mobile Application. Specific activities include: Preparation of Usability Study Protocol and Questionnaires, SAP, DM Plan and eDatabase (WBS 1.2.3.5.1 – 1.2.3.5.6); Site qualification and selection for both the Usability (WBS 1.2.3.5.7); Site contracts and IRB approvals for both the Usability (WBS 1.2.3.5.8 – 1.2.3.5.10); Site preparation and initiation for the Usability and (WBS 1.2.3.5.11 – 1.2.3.5.12); Execution of Usability Study (WBS 1.2.3.5.13); Data management, analysis, reporting, and close-out for both studies (WBS 1.2.3.5.14 – 1.2.3.5.16). Deliverable is Usability Study report.

**WBS/IMS 1.2.3.6: Clinical Study Protocols, SAPs, Data Management Plans, eDatabases.** Specific tasks include: preparation of separate protocols for Method Comparison, Reproducibility/Repeatability, Samples at LoD studies (WBS 1.2.3.6.1); preparation of Statistical Analysis Plans (WBS 1.2.3.6.2); preparation of Data Management Plans (DMPs) and eDatabases (WBS 1.2.3.6.3 – 1.2.3.6.4). Deliverables are internal approval of the protocols for the Method Comparison Study, Reproducibility/ Repeatability Study, and Samples at LoD Study, SAPs, and DMPs, and live eDatabases.

**WBS/IMS 1.2.3.7 – 1.2.3.8: Clinical Study Sites/Central Lab Qualification.** Specific activities include: development of site feasibility questionnaire, identification of potential sites, execution of non-disclosure agreement with potential investigators, conduct site qualification visits and reporting (WBS 1.2.3.7.1 – 1.2.3.7.8, WBS 1.2.3.8.1 – 1.2.3.8.8). Deliverables are at least 8 clinical sites and 1 central lab selected.

**WBS/IMS 1.2.3.9: Clinical Study Site Contracts.** Specific activities include: draft budgets and budget negotiation (WBS 1.2.3.9.1); draft contract and contract negotiations (WBS 1.2.3.9.2).

Deliverables are clinical study contracts executed with clinical sites and central lab. Deliverables are clinical study contracts executed with clinical sites and central lab.

**WBS/IMS Task 1.2.3.10: Institutional Review Board (IRB) Submissions and Approvals.** Specific activities include: selection of IRB, completion of IRB protocol submission forms, draft informed consent forms, and submission and approval of method comparison study protocols and informed consent forms (WBS 1.2.3.10.1 – 1.2.3.10.6). Deliverables are IRB approval of Method Comparison, Reproducibility/Repeatability Study, and Samples at LoD Protocols.

**WBS/IMS Task 1.2.3.11: Clinical Study Materials.** Specific tasks include: ship Cue IUO devices, mobile smart devices, predicate devices and sample collection kits procurement and accountability at clinical sites (WBS 1.2.3.11.1 – 1.2.3.11.11). Deliverables are all clinical study materials at the clinical sites.

**WBS/IMS Task 1.2.3.12: Clinical Site Initiation.** Specific tasks include: preparation of Clinical Monitoring Plans, set up of Trial Master Files and Investigator Site Binders, creation of study-specific forms, conduct site initiation visits and preparation and approval of initiation visit reports (WBS 1.2.3.12.1 – 1.2.3.12.2). Deliverables are clinical sites initiated.

**WBS/IMS Task 1.2.3.13.1 – 1.2.3.13.4: Reproducibility/Repeatability Studies.** This study will demonstrate the reproducibility and repeatability of the Cue Multiplex Respiratory Pathogen Cartridge at external clinical sites. The study will be conducted at 3 external sites with trained professional operators using identical panel members. A 13-member sample panel will be prepared in a simulated nasal swab sample matrix. One panel member will be negative for influenza A, influenza B, RSV and HCoV. The positive panel members will contain these viruses at high negative ( $C_{20-80}$ ), low positive ( $C_{95}$ ), and moderate positive (2-3x LoD) concentrations. Each positive panel member will contain only one type of virus (eg, influenza A or influenza B or RSV or HCoV). At each site, 2 operators per day will conduct testing. Each operator will test 3 replicates of each sample panel member per run. Each site will conduct testing for 5 days. Each site will generate 30 results per sample for a total of 90 results per sample overall. Specific activities include study execution (WBS 1.2.3.13.1); database lock and data review and analysis (WBS 1.2.3.13.2); study close-out (WBS 1.2.3.13.3; 1.2.3.13.7), preparation of study report (WBS 1.2.3.13.4). Deliverable is the study report.

**WBS/IMS Subtasks 1.2.3.13.5 – 1.2.3.13.8: Clinical Sites Testing of Samples with Concentrations near the LoD.** This study will demonstrate the performance of the Cue Multiplex Respiratory Pathogen Cartridge with untrained professional users testing samples with near the LoD. The study will be conducted at 3 external CLIA Waived clinical sites. For influenza A, influenza B, RSV or HCoV concentrations sample panels, Cue will prepare a contrived weak positive ( $C_{95}$ ) sample pool and a contrived weak negative ( $C_5$ ) sample pool in a simulated nasal swab sample matrix. The aliquots of the pools will be distributed (minimum 10/operator) to the sites for testing. Two untrained operators at each site will conduct testing. The percent of positive results with Cue Multiplex Respiratory Pathogen Cartridge for the weak positive samples and the percent of negative results for the weak negative samples will be calculated overall and by site. Specific activities include study execution (WBS 1.2.3.13.5); database lock and data review and analysis (WBS 1.2.3.13.6); study close-out (WBS 1.2.3.13.7), preparation of study report (WBS 1.2.3.13.8). Deliverables is the Samples at LoD study report.

**WBS/IMS Task 1.2.3.14: Clinical Performance/Method Comparison Study including Human Factors/Usability**  
The objective of the Method Comparison is to establish the clinical performance of the Cue Health Monitoring System with the Cue Multiplex Respiratory Pathogen Cartridges and the Cue Health Mobile App in comparison to the reference/predicate device(s). The purpose of the Human Factors/Usability element of this study is to assess user interactions with the Cue device user interface to identify any residual use errors that would or could result in serious harm to the patient or operator. The Human Factors/Usability validation will be incorporated into the

Method Comparison study with participating lay users completing a usability questionnaire (developed by Cue). This study will be designed in consideration of FDA feedback to be received during the pre-submission, FDA's "Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA)

Waiver Applications for Manufacturers of In Vitro Diagnostic Devices," "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses," "Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays", "Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices" and applicable FDA regulations. This prospective, non-interventional clinical performance study will be conducted at approximately 8 US clinical sites. The study population will include subjects of all ages with signs and symptoms of respiratory infection. To generate data in support of the OTC claim, the clinical study will enroll lay users who will self-collect their own mid-turbinate nasal swab sample using the Cue sample wand and self-test in the Cue Multiplex Respiratory Pathogen Cartridge test. The study will also enroll parents collecting and testing his/her enrolled child's nasal sample. The overall sample size of 2000 subjects is dependent on the prevalence of influenza viruses, RSV, and HCoV which vary by season. The overall sample size is approximately 2,000 subjects to obtain a minimum of 120 samples with positive results for influenza A, 120 samples with positive results for influenza B, approximately 40 samples with positive RSV results, and 40 samples with positive human coronavirus results as determined by the reference method. The overall sample size assumes that influenza B and coronaviruses will have the lowest prevalence, assuming 6% for influenza B and 2% for human coronaviruses. Cue Multiplex Respiratory Pathogen Cartridge results will be compared to the predicate method(s) (eg, respiratory panel NAAT assay) and sensitivity and specificity of the Cue Multiplex Respiratory Pathogen Cartridge test will be calculated. Specific tasks include: execution and reporting of the method comparison study (WBS 1.2.3.14.1 – 1.2.3.14.4).

Deliverable is the clinical study report.

**WBS/IMS Task 1.2.3.15: BIMO Inspections.** Specific activities include clinical site and Cue preparation and mock inspections (WBS 1.1.3.15.1 – 1.1.3.15.2). Deliverable is mock BIMO inspections completed.

#### **REGULATORY (WBS 1.2.4):**

##### **WBS/IMS Tasks 1.2.4.1 – 1.2.4.3: Regulatory Submissions.**

Preparing and submitting FDA Pre-submissions for OTC Cue Multiplex Respiratory Pathogen Cartridge (WBS 1.2.4.1); preparing and submitting FDA 510k submission for OTC Cue Multiplex Respiratory Pathogen Cartridge (WBS 1.2.4.2). Deliverables are FDA 510k submission and clearance.

#### **BIOPRODUCTION MANUFACTURING (WBS 1.2.5):**

Bioproduction Manufacturing activities include enzyme and lyophilization process scale up, design freeze, validation and process transfer to GMP. These activities will take place after assay verification and result in a fully validated lyophilization process for production of cartridge lots for analytical and clinical validation studies.

**WBS/IMS 1.2.5.1: Enzyme Process Transfer and Validation.** Enzyme processes and specifications will be finalized and documentation completed. Upon completion of document approvals, the process validation of the enzyme processes will begin. After 3 successful preproduction lots of enzymes are made, the validation study of each enzyme process will be completed and reviewed. Lyophilization process

development and verification will be conducted. Specific activities include preparation of enzyme process validation protocol, manufacture of enzymes and completion of validation report (WBS 1.2.5.1.1 – 1.2.5.1.6). Deliverable is enzyme process validation report.

**WBS/IMS 1.2.5.2: Lyophilization Process Development and Verification.** Lyophilization scale up process development, manufacture of 3 lots of reagent pellets and accelerated stability studies will also be performed on each enzyme lot generated (WBS 1.2.5.2.1 – 1.2.5.2.6). Deliverable is 3 preproduction lots of enzyme passing QC Specifications.

**WBS/IMS 1.2.5.3: Lyophilization Formulation Lock and Design Freeze.** Production lots of lyophilization pellets will be made, the lyophilization formulation will be locked and design freeze will be completed. Specific activities include preparation of internal certificate of analysis for

production lots, preparation of process transfer protocol, and transfer to GMP (WBS 1.2.5.3.1 – 1.2.5.3.5). Deliverable is process transfer protocol.

**WBS/IMS 1.2.5.4: Lyophilization Process Transfer and Validation.** After 3 successful pre-production lots of lyophilization pellets are made, the lyophilization process validation will be completed. After the completion of lyophilization validation, the lyophilization process will be integrated into the automation line to support manufacturing of Cue Multiplex Respiratory Pathogen Cartridges for analytical and clinical validation. Specific activities include preparation of internal certificate of analysis for production lots, preparation of process transfer protocol, and transfer to GMP. The validation protocols for the lyophilization process will be prepared and IQ, OQ, and PQ validation efforts will be completed. Critical process parameters will be identified through FMEA risk assessments (WBS 1.2.5.4.1 – 1.2.5.4.8).

Deliverable is the lyophilization validation report.

**WBS/IMS 1.2.5.5 Bioproduction scale-up for post 510k commercialization.**

#### **CARTRIDGE AUTOMATION MANUFACTURING (WBS 1.2.6):**

Cartridge Automation Manufacturing activities include automation system design, approval, fabrication of manufacturing systems, validation of cartridge automation line and manufacture of Cue Influenza Cartridges for analytical and clinical validation. The systems that encompass the automation line for cartridge manufacturing are: 1500- System Drawing of PCB Processing Machine, 1501- PCB/Fluidic Subassembly Machine, 1502- Flavoring Machine, 1503- Finishing Machine, 1504- Cartridge Printing Machine, 1505- Cartridge Pouching Machine, 1506- Lyophilized Bead Dispense System, 1507- Fluid Wand Assembly Machine, 1701- Fluidic/PCB Assembly Machine, 1708- Fluidic Pre-Processing Machine and 1709- Wax-Dispense System.

**WBS/IMS 1.2.6.1: Create system level drawings for each automation system/machine.**

Deliverable is completed system-level drawing for each automation machine.

**WBS/IMS 1.2.6.2: Write specification for each automation machine.** Deliverable is system-level specifications for each automation machine.

**WBS/IMS 1.2.6.3: Project approval for each system.** Deliverable is documented project approval for each system.

**WBS/IMS 1.2.6.4: Successful Design Review for Each System.** Deliverable is documented design review and approval completed for each system.

**WBS/IMS 1.2.6.5: Install Dry Room System for Manufacturing Cell.** Deliverable is documented validation for dry room performance.

**WBS/IMS 1.2.6.6: Fabrication of Each System (mechanical, electrical, pneumatics).**

Deliverable is fabrication of each system is completed.

**WBS/IMS 1.2.6.7: Initial Debug of Each System (able to produce a single part).**

Deliverable is each system debug is completed.

**WBS/IMS 1.2.6.8: Full System Runs-Optimize and Final Debug.** Deliverable is optimization and final debug completed.

**WBS/IMS 1.2.6.9: Documentation for Each System (e.g., Operation & Maintenance Manual, Spare Parts List).** Deliverable is documentation for each system is complete.

**WBS/IMS 1.2.6.10: Validation Protocols for Each System.** Deliverable is approved validation protocols for each system.

**WBS/IMS 1.2.6.11: Validate all Systems (IQ, OQ, PQ).** Deliverable is IQ, OQ, PQ complete and report approved for each system.

**WBS/IMS 1.2.6.12: Manufacture of Cue Multiplex Respiratory Pathogen Cartridge for analytical and clinical validation.** Manufacture of 3 lots of Cue Multiplex Respiratory Pathogen Cartridge for analytical and clinical validation.

**WBS/IMS 1.2.6.13: Manufacture scale up to meet cartridge sales post FDA 510(k) clearance WBS/IMS 1.2.7: Quality:** Maintenance of ISO 13485 certification, quality audits, instrument calibrations, QA and release batch records, oversee building management

**WBS/IMS 1.2.8 Operations:** ERP, purchasing, supply chain and inventory management, production/quality team coordination.

**WBS/IMS 1.2.9 Software:** Develop testing systems for iOS consumer and professional apps, software verification/validation/documentation, automated testing to ensure working order systems. Deliverable is validated Cue consumer and professional apps and ongoing software lifecycle documentation.

## ATTACHMENT #8

### Background Inventions

The following table provides a list of inventions which may be used in the performance of the contract but to which the Government shall have no rights because they were developed at private expense prior to the effective date of the contract (the "Background Inventions"):

Patent/Application No	Publication Date	Title
US9034168	May 19, 2015	Systems and methods for detection and quantification of analytes
US9052275	June 9, 2015	Systems and methods for detection and quantification of analytes
US9086417	July 21, 2015	Systems and methods for detection and quantification of analytes
US9207244	December 8, 2015	Systems and methods for detection and quantification of analytes
US9207245	December 8, 2015	Systems and methods for detection and quantification of analytes
USD745423	December 15, 2015	Automated analyzer test cartridge and sample collection device for analyte detection
USD77407S1	December 20, 2016	Cartridge of an analyte detection system
CA2904135 A1	October 9, 2014	Systems and methods for detection and quantification of analytes
US9522397 B2	December 20, 2016	Systems and methods for detection and quantification of analytes
US9360491 B2	June 7, 2016	Systems and methods for detection and quantification of analytes
US9636676 B2	May 2, 2017	Systems and methods for detection and quantification of analytes
USD789815	June 20, 2017	Reader of an analyte detection system
US9718058	August 1, 2017	Cartridges, kits, and methods for enhanced detection and quantification of analytes
US9808804	November 7, 2017	Cartridges, collectors, kits, and methods for enhanced detection and quantification of analytes in collected fluid samples
US9724691	August 8, 2017	Cartridges, kits, and methods for enhanced detection and quantification of

		analytes
US9623409	April 18, 2017	Cartridges, kits, and methods for enhanced mixing for detection and quantification of analytes
US9789483	October 17, 2017	System for portable and easy-to-use detection of analytes with mobile computing device

For purposes of FAR 52.227-14, Rights in Data, Alt II, all unpublished data pertaining to the above Background Inventions that is not first produced in the performance of the contract shall be considered "limited rights data."